The Feasibility and Acceptability of a Behavioural Activation Intervention for Young People with Depression in Child and Adolescent Mental Health Services

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The Feasibility and Acceptability of a Behavioural Activation Intervention for Young People with Depression in Child and Adolescent Mental Health Services

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Abstract

Depression in young people is common, resulting in morbidity and mortality. Behavioural Activation (BA) is a cost-effective and efficacious treatment for reducing depressive symptoms in adults. There is little published research relating to BA as a treatment option for young people with depression. Thus, the aim was to explore the feasibility of conducting a trial of BA for depression in Child and Adolescent Mental Health Services (CAMHS).

Stage I

The initial stage of the study comprised a focused ethnography, conducted over a six-month period. The purpose was to explore the CAMHS study site, with a view to pre-empting (and addressing) any difficulties that may be encountered during a planned trial. Participant observation (158 hours), staff interviews (n= 6) and document collection (n= 17) were used to gather data. Data were coded using thematic analysis and the resulting themes were verified by a second coder. Insights into the individual, practical and organisational boundaries of the service guided implementation of Stage II.

Stage II

The second stage involved a randomised controlled feasibility trial with an embedded qualitative component. Participants were identified via a case note review or self/clinician referral from three CAMHS over seventeen months. Young people (aged 12 to 17 years) displaying symptoms of depression were offered a structured diagnostic interview to confirm depression status. Additional measures of mood, functioning and self-esteem were recorded. Twenty-two patients were randomised to BA or usual CAMHS care. Existing CAMHS staff were trained to deliver

the 8-week manualised BA intervention. Following treatment, participants in the BA arm, their parents and clinicians were offered semi-structured interviews to explore their experiences of receiving or administering BA. Verbatim interview transcripts were coded using thematic analysis. At three months post-baseline, the diagnostic interview and outcome measures were repeated. At six months post-baseline, a telephone interview repeated selected outcomes.

Participant recruitment was successful but the trial suggests that the process used could be streamlined. Participants were 82% female, with a mean age of 15.7 (SD, 1.2) years. Qualitative feedback from patients and their caregivers supported the acceptability of BA treatment. Families also identified barriers to participating in the intervention. Most staff found the intervention acceptable, but some raised concerns about the manualised treatment delivery. Retention at three months was 68%, with higher loss to follow-up in the BA (4/11; 36%) vs. usual care (3/11; 27%). Although not powered to demonstrate statistical differences, preliminary quantitative data suggest BA treatment may result in improved outcomes compared to usual care, such as remission from depression. Fewer BA participants met depression criteria at three-month follow-up (3/7; 42.9%) than in usual care (7/8; 87.5%). However, the assessor was not blinded to treatment allocation, fidelity was not assessed and the number of sessions was not controlled for, which increases uncertainty relating to the results.

This research contributes valuable information about how a BA trial could be implemented in an adolescent mental health setting, and provides indications about the potential of the approach to treat depression in this context. However, outstanding questions relating to the feasibility of the intervention remain.

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Adolescents Taking Action (ATA) Manual

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Behavioural Activation (BA)

Behavioural Activation for Depression Scale (BADS)

Behavioural Activation for Depression (BATD)

Behavioural Activation for Major Depressive Disorder in Youth (BUDDY) Study

Behavioural Activation in Young People- A Feasibility Study in Primary Care (BAY-F)

Body Mass Index (BMI)

Child and Adolescent Mental Health Services (CAMHS)

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Children's Depression Rating Scale- Revised (CDRS-R)

Children's Global Assessment Scale (CGAS)

Cognitive Behavioural Therapy (CBT)

Confidence Interval (CI)

Consolidated Standards of Reporting Trials (CONSORT)

Diagnostic and Statistical Manual of Mental Disorders (DSM)

Health of the Nation Outcome Scales for Children and Adolescents (HoNOSCA)

Improving Access to Psychological Therapies (IAPT)

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International Classification of Diseases (ICD)

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Multiple Imputation (MI)

National Health Service (NHS)

National Institute for Health and Clinical Excellence (NICE)

National Institute for Health Research (NIHR)

Patient and Public Involvement (PPI)

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Primary Mental Health Worker (PMHW)

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Routine Outcome Measure (ROM)

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Selective Serotonin Reuptake Inhibitor (SSRI)

Standard Deviation (SD)

Tees, Esk and Wear Valleys (TEWV)

Treatment As Usual (TAU)

Treatment for Adolescents with Depression Study (TADS)

Statement of Copyright

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and passion for academia, psychiatry, psychology, health, nursing, anthropology, research methods and writing. Learning from their varied skillsets has helped me to find the beginnings of my own niche, it has fuelled my passion for health services research and I hope that I have done their guidance justice.

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Dedication

I would like to dedicate this thesis to the memory of Professor Anne Campbell (1951-2017), who continues to be a great source of inspiration to me.

Publications from this thesis

Journal papers

Kitchen, C. E. W., Lewis, S., Tiffin, P. A., Welsh, P. R., Howey, L. & Ekers, D. (2017) A focused ethnography of a Child and Adolescent Mental Health Service: factors relevant to the implementation of a depression trial. *Trials*, 18: 237.

Journal papers in preparation

Kitchen, C. E. W., Ekers, D., Tiffin, P. A. & Lewis, S. (in preparation) Short report: A Randomised Controlled Feasibility Trial of Behavioural Activation as a Treatment for Young People with Depression in Child and Adolescent Mental Health Services. *Br J Psychiatry*.

Kitchen, C. E. W., Lewis, S., Ekers, D. & Tiffin, P. A. (in preparation) Behavioural Activation for Young People with Depression in Child and Adolescent Mental Health Services: A Qualitative Exploration Embedded within a Randomised Controlled Trial. *Child Adolec Ment Health*.

Conference contributions

Kitchen, C. E. W., Ekers, D., Tiffin, P. A. & Lewis, S. (2016) Behavioural Activation Therapy for Young People with Depression in UK Child and Adolescent Mental Health Services: A Feasibility Study, *8th World Congress of Behavioural and Cognitive Therapies, 22nd-25th June 2016*. Melbourne Convention and Exhibition Centre, Australia.

Kitchen, C. E. W., Ekers, D., Tiffin, P. A. & Lewis, S. (2016) Behavioural Activation Therapy for Young People with Depression in Child and Adolescent Mental Health Services, *School of Medicine, Pharmacy and Health Postgraduate Conference, 10th June 2016*. Durham University, UK.

Kitchen, C. E. W. (2016) Invited Co-Chair for Oral Session 4. *Wolfson Research Institute for Health and Wellbeing Early Stage Researcher Conference, 8th June 2016*. Durham University, UK.

Kitchen, C. E. W., Ekers, D., Tiffin, P. A. & Lewis, S. (2016) Behavioural Activation Therapy for Young People with Depression in Child and Adolescent Mental Health Services: A Feasibility Study, *Wolfson Research Institute for Health and Wellbeing Early Stage Researcher Conference, 8th June 2016.* Durham University, UK.

Kitchen, C. E. W., Lewis, S., Tiffin, P. A., Welsh, P. R. & Ekers, D. (2015) Child and Adolescent Mental Health Services: A Focused Ethnography to Inform the Design of a Randomised Controlled Trial, *Postgraduate Methods Challenge, 1st July 2015.* Durham University, UK.

Kitchen, C. E. W., Tiffin, P. A., Ekers, D., Welsh, P. R. & Lewis, S. (2015) Behavioural Activation for Major Depressive Disorder in Young People: the BUDDY Study, *School of Medicine, Pharmacy and Health Postgraduate Conference, 16th June 2015*. Durham University, UK.

Kitchen, C. E. W., Tiffin, P. A., Ekers, D. & Welsh. P. R. (2015) A Protocol for a Randomised Feasibility Study of Behavioural Activation for Young People with Depression in Child and Adolescent Mental Health Services, *Wolfson*

Research Institute for Health and Wellbeing Research Colloquium, 15th April 2015. Durham University, UK.

Kitchen, C. E. W., Tiffin, P. A., Ekers, D. & Welsh. P. R. (2014) Behavioural Activation as a Treatment for Young People with Depression in Child and Adolescent Mental Health Services, *Tees, Esk & Wear Valleys Mental Health Research & Development Annual Conference, 14th March 2014.* Durham University, UK.

Other dissemination presentations

Kitchen, C. E. W. & Ekers, D. (2016) Behavioural Activation Therapy for Young People and Adults with Depression, *Child and Adolescent Mental Health Quality and Assurance Group, 3rd May 2016*. North Durham Child and Adolescent Mental Health Services, UK.

Kitchen, C. E. W., Tiffin, P. A., Ekers, D. & Lewis, S. (2015) Behavioural Activation Therapy for Young People with Depression in Child and Adolescent Mental Health Services, *Child and Adolescent Mental Health Service Psychology Meeting CPD Slot, 2nd September 2015*. Lanchester Road Hospital, UK.

Kitchen, C. E. W., Tiffin, P. A., Ekers, D. & Welsh, P. R. (2014) A Protocol for a Randomised Feasibility Study of Behavioural Activation for Young People with Depression in Child and Adolescent Mental Health Services, *Behavioural Activation Symposium, 17th October 2014*. Durham University, UK.

Introduction

At the outset, I envisaged this PhD project would be a purely quantitative endeavour; a pilot Randomised Controlled Trial (RCT) that would evaluate Behavioural Activation (BA) as a treatment for young people with depression in Child and Adolescent Mental Health Services (CAMHS). This expectation was primarily based on learning about RCTs as the 'gold standard' of research, along with the ubiquity of RCT evidence in the clinical practice guidelines (Torgerson and Torgerson, 2008, National Institute for Health and Clinical Excellence, 2005). However, once I initiated the background literature review it quickly became clear how little published research there was relating to BA for children and young people. There were many outstanding questions relating to the feasibility of a BA approach, particularly in a UK CAMHS context. Alongside this were the inherent differences across cultures and contexts in the definitions of the terms 'child', 'adolescent' and 'young person'. In relation to the potential use of BA in UK clinical practice, I appraised different research methods and methodologies and considered whether a purely qualitative approach would be a more suitable design to answer my research questions. As qualitative research is concerned with how the social world is interpreted, understood, experienced, produced or constituted (Mason, 2002), it seemed to be well suited to answering questions relating to the acceptability and feasibility of a novel intervention from a patient and practitioner perspective. However, I rejected this approach because later questions that would need to be tackled, relating to the efficacy of the intervention, would not best be served by a solely qualitative paradigm. Yet again, however, relying on an efficacy-based

paradigm (such as an RCT) that has been established to answer questions under decontextualisation or in optimal conditions would not produce the solutions needed for clinical practice (Kessler and Glasgow, 2011). Thus, neither a qualitative or quantitative approach alone would have accounted for the complexity of the subject, nor responded to the lack of evidence in the area. This led me to decide upon a mixed methods approach (Cresswell, 2009), which brought with it an inimitable set of challenges.

This thesis embraces qualitative and quantitative approaches which are clearly derived from differing ontological and epistemological standpoints. A person's ontological perspective refers to their view of the world and what they believe constitutes a social 'reality' (Savage, 2000, Mason, 2002). A person's epistemological position communicates what they regard as evidence or knowledge in relation to these social realities (Mason, 2002, Barber, 2014). There has been much debate between both qualitative and quantitative researchers about what constitutes a reality and much discussion from mixed methods researchers about how to deal with these differences (Sale et al., 2002). Rather than selecting one rigid viewpoint, Mason (2002) argues that it is more productive to learn what we can from debates about the ability of research to uncover truths or to represent the realities of others, rather than to assume one argument has authority over another (Mason, 2002). Sale, Lohfeld and Brazil (2002) caution against combining qualitative and quantitative methods uncritically, without considering the underlying assumptions inherent in each approach. These differing standpoints have not only presented a challenge when designing and delivering this research, but also during the analysis and presentation of the results. Quantitative and qualitative approaches

each engender and are associated with a particular style of writing; quantitative styles often comprising of brief, segmented script with short sentences. Qualitative research, in contrast, is often textured as a thick narrative composition (Ponterotto, 2006). Mixed methodologists have long discussed ways to successfully report and integrate such methods within the same study (Cresswell, 2009). However, the challenge in writing this thesis was guiding the reader through chapters that are written in contrasting styles.

Overview

A visual thesis map has been created to guide the reader through the research process and resulting thesis (see Figure 1). The stepped 'stages' mirror the 'phased' approach to evidence building commonly seen in RCTs and in recommendations issued in relation to trial design (for example, the Medical Research Council [MRC] guidance), which will be discussed in more detail throughout the thesis (Craig et al., 2008). The scoping background literature review includes research relating to adults, young people and children of all ages. In the later stages of the thesis (Stage II), a narrower age range of young people (aged 12 to 17) has been focused upon. Stage I of this thesis describes how a focused ethnographic approach was used to inform Stage II of the research (a feasibility RCT). This focused ethnography has been published in a peer-reviewed, academic journal as an illustration of the innovative approach that was taken to sequencing mixed methods in the context of the trial design (Kitchen et al., 2017). The contextual information gained from Stage I was invaluable in understanding the boundaries into which the trial for Stage II of the research was to be implemented. Within the trial protocol for Stage II, both

quantitative and qualitative methods have been selected to measure symptom severity and explore the lived experience of the BA treatment through the accounts of young people, their parents/carers and clinicians. As such, it is important to emphasise how these apparently disparate approaches have been combined into a coherent piece of research that acknowledges the inherent diversity of the methods used.

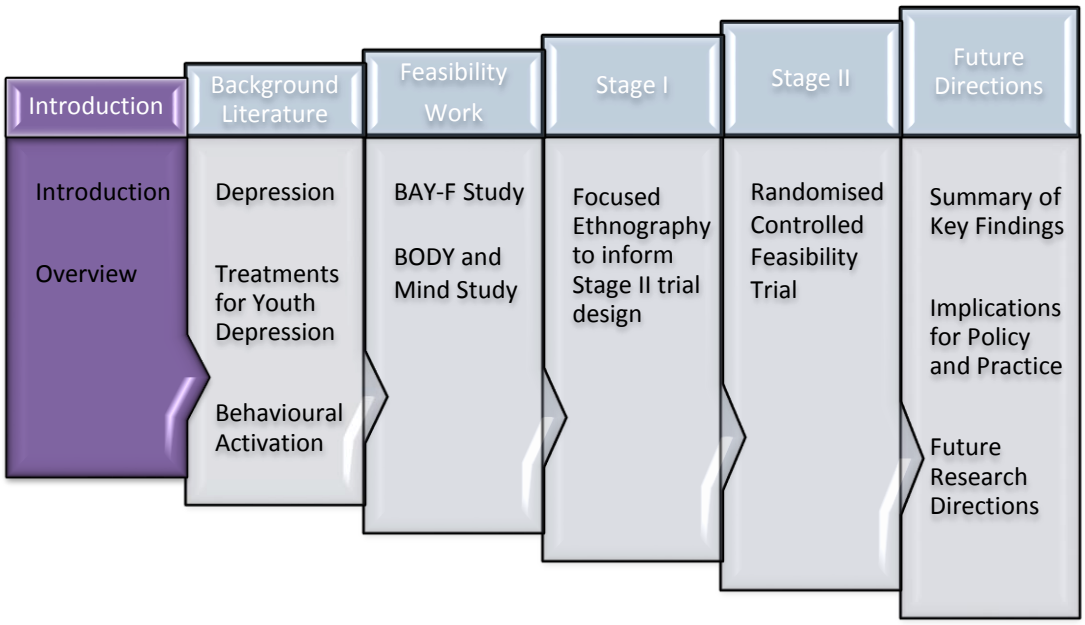


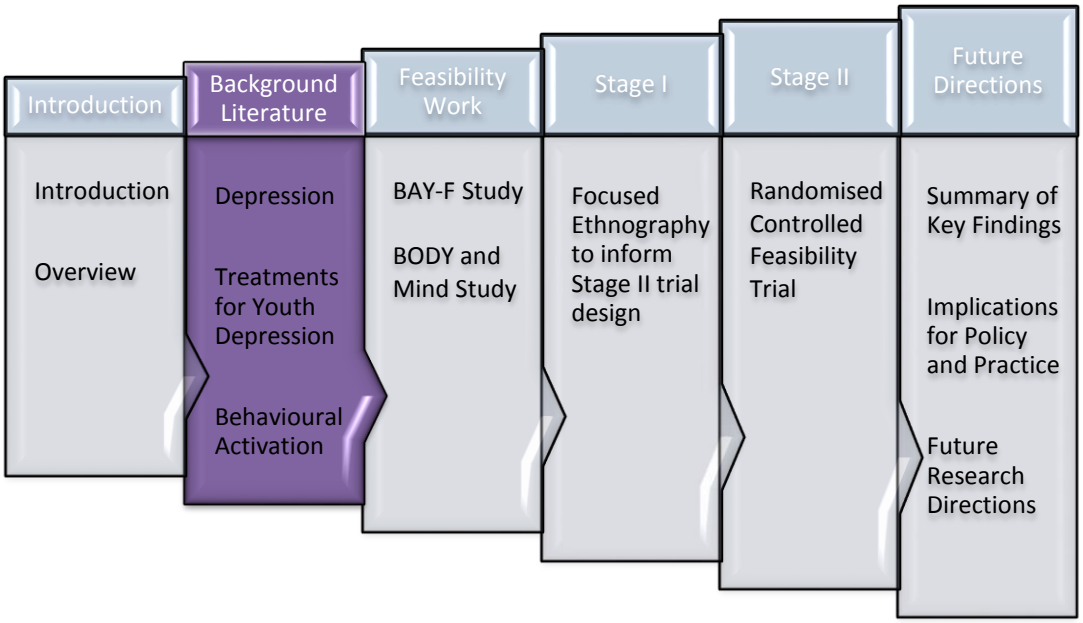
Figure 1: Thesis map: current chapter highlighted in purple

One research tool that has helped achieve this coherence is reflexivity. Mason (2002) describes reflexivity as the process of thinking critically about what you are doing and why you are doing it. Reflexivity aids researchers in considering their motivations, personal experiences and inside knowledge of the setting, all of which can affect the way researchers conduct research (Wells et al., 2012). This was important in the context of my PhD research, because I have previously undertaken training in the intervention of interest (BA) and have prior experience of working in a

positivist trial environment, which could have led me towards biased expectations or judgements. As it was, being reflexive allowed me to acknowledge and account for inherent factors that might otherwise impact upon the rigour and, ultimately, the quality and utility of the research. Although this technique is most usually associated with qualitative research, it has been suggested that the application of reflexivity to quantitative research endeavours can promote transparency around the conduct and reporting of RCTs by providing a more accurate account of trial delivery (Wells et al., 2012). This is important because complex interventions, such as BA, are likely to produce complex outcomes (Kessler and Glasgow, 2011). Distinct but complimentary quantitative (structured outcome measures) and qualitative (interviews) methods were selected in Stage II of this research to account for this complexity. Consequently, I felt that there was value in applying a reflexive approach to my whole study. As a result, I was able to ask critical questions of myself and my research.

This thesis begins with a traditional background literature review (Chapter 1), followed by a discussion of unpublished research in the area (Chapter 2). The subsequent chapter (Chapter 3) details the first study completed as part of my doctorate; the chapter describes purely qualitative research and is written in an ethnographic style. The next chapter (Chapter 4), which forms the main body of this thesis, is a mixed methods trial, which is reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidance for the reporting of RCTs. Within this chapter the qualitative and quantitative results are reported on separately, in order to clearly delineate the learning from each method employed. The findings are then discussed in an integrated discussion at the end of the chapter. The final

chapter (Chapter 5) is an overview of the key learning from this doctoral research, written in a more personally reflective style.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Chapter 1 Background Literature

This literature review is not systematic in nature, as from the outset I was aware of a systematic review, being undertaken at York University, of Behavioural Activation (BA) as a treatment for youth depression. Instead, a 'scoping review' was conducted to inform the research described within this thesis. A scoping review can be described as a narrative integration of the relevant evidence and can be particularly useful where there has been no knowledge-synthesis to date (Pham et al., 2014), as was the case at the start of my PhD. There is a lack of consensus on the methodology that should be used within scoping studies (Colquhoun et al., 2014) but I followed best practice guidance by using a formal search strategy in relation to this aspect of the literature review by searching for key words relating to BA and young people, across MEDLINE, EMBASE, PsycINFO, CINAHL and Cochrane Library databases. The scoping review presented below, focuses on literature relevant to the discussion of BA as a treatment for depression. It does not include literature related to the methods or methodology used in the research conducted as part of this thesis, as this additional literature will be discussed in the relevant chapters.

This chapter starts by providing an overview of depression and then focuses on depression specifically in children and young people. An overview of treatments for depression in this population is then provided, followed by the rationale for considering BA as one such treatment. The application of BA to adults and children will then be discussed and the current literature summarised.

Depression

Across all societies, mental health conditions represent a substantial proportion of ill health (Patel et al., 2007). Depression is one such disorder, the prevalence and persistence of which has been linked to severely impaired quality of life and, in some cases, suicide (Kessler and Bromet, 2013, World Health Organization, 2017). In 2015, depression was ranked by the World Health Organization as the leading contributor to global disability, accounting for 7.5% of the total years lived with disability (World Health Organization, 2017). Globally, 300 million people were estimated to suffer from depression in 2015, equating to 4.4% of the world's population (World Health Organization, 2017). In fact, depression is projected to be the second largest cause of world disease burden by 2020 and the primary cause by 2030 (World Health Organization, 2001, 2013). However, although depression is common worldwide, lifetime prevalence estimates are higher in wealthier countries, such as the UK (Kessler and Bromet, 2013). In England, in 2007, the economic cost of depression was estimated to be £1.7 billion and this is predicted to rise to £3 billion by 2026 (National Institute for Health and Clinical Excellence, 2009a).

The term depression came into regular use towards the end of the eighteenth century but has many different connotations (Goodyer, 2001), as illustrated below. Clinically, the term refers to symptoms and behaviours relating to changes in mood, thinking and activity, that are substantial enough to impair functioning (National Institute for Health and Clinical Excellence, 2005).

depression noun (unhappiness)(Cambridge University Press, 2017)

the state of feeling very unhappy and without hope for the future: *I was overwhelmed by feelings of depression.*

a mental illness in which a person is very unhappy and anxious (worried and nervous) for long periods and cannot have a normal life during these periods: *Tiredness, loss of appetite, and sleeping problems are all classic symptoms of depression.*

clinical depression noun (Cambridge University Press, 2017)

a mental illness that causes feelings of sadness and loss of hope, changes in sleeping and eating habits, loss of interest in your usual activities, and pains that have no physical explanation.

Depression is a diagnosable health condition and as such is distinct from the usual transient feelings of sadness or stress that most of the population experience at some point in their lifetimes (World Health Organization, 2017). Symptoms of depression can last from a few weeks upwards (World Health Organization, 2017). Although the root causes are, as yet, unclear, depression is understood to result from a complex interaction of social, biological and psychological factors (World Health Organization, 2001, Dwivedi and Varma, 1997). People who have experienced adverse life events are more likely to develop depression, and it can lead to subsequent life difficulties and worsened ability to cope with existing struggles (World Health Organization, 2001).

The International Classification of Diseases (ICD-10) and the Diagnostic and Statistical Manual of Mental Disorders- Fifth Edition (DSM-V) are recognised as the two main classification systems for mental and behavioural disorders (World Health

Organization, 1992, American Psychiatric Association, 2013). In the ICD-10, depression is included under Mood (Affective) Disorders (F30-F39) and in the DSM-V clinical depression is known as Major Depressive Disorder (MDD). Central features shared across both categorisations are a change in affect or mood and, depending upon the number and severity of the symptoms, a depressive episode may be specified as mild, moderate or severe.

Depression in children and young people

Depression is already the leading cause of illness and disability in young people (World Health Organization, 2014a). Depression occurs in children and adolescents below the age of 15 years, but at lower rates than those reported in older age groups (World Health Organization, 2017). Observers had previously reported increases in the prevalence of depression in children and adolescents, evidenced by adolescent and adult cohort studies, as well as increases in rates of youth antidepressant prescribing (Kessler et al., 2003, Zito et al., 2003, Collishaw et al., 2004). However, this was refuted by a large meta-analysis of studies conducted over a 30-year period, which found no evidence that children and adolescents born today were more likely than those from earlier generations at the same age to suffer from depression (Costello et al., 2006).[1] Yet even if it is the case that the incidence of depression is not increasing, the disorder remains strikingly common in young people; current prevalence rates for children under 13 are estimated to be 2.8%, increasing markedly to 5.7% for adolescents aged 13 to 18 years old (Costello et al., 2006). Gender differences are also evident with depression being considerably more

[1] A meta-analysis is a quantitative technique to provide a synthesis of the evidence, with the effects of multiple studies pooled to generate an overall picture of average treatment impact (Rutter et al., 2008).

common in adolescent girls (5.9%) than adolescent boys (4.6%) (Costello et al., 2006).

There is general agreement that child and adolescent depression shares many similarities with adult depression (Birmaher et al., 1996, Dwivedi and Varma, 1997). Depression in children and young people is characterised by persistent and pervasive sadness, anhedonia, boredom and/or irritability (Weisz et al., 2005). On an individual level, childhood depression can be long lasting, and extremely disabling (Birmaher et al., 1996); it is this functional impairment that separates depression from normal teenage mood swings (Weisz et al., 2005). Those diagnosed with depression experience high rates of self-harm and suicide (Patel et al., 2007) and tragically, suicide is now the leading cause of death in young women (aged 15 to 19) in Europe, overtaking deaths related to maternal mortality for the first time (World Health Organization, 2014b). Less is known about the numbers of children aged under 15 who attempt suicide, due to a lack of official statistics (National Society for the Prevention of Cruelty to Children, 2014). There is a strong relationship between poor mental health and reduced educational achievement, substance use, poor reproductive and sexual health outcomes and becoming a victim of violence (Birmaher et al., 1996, Patel et al., 2007). Moreover, depression in childhood often reoccurs during adulthood (Birmaher et al., 1996). This is compounded by the fact that the biggest risk factor for suicide is a previous attempt (World Health Organization, 2014b). Hence, mental illness in childhood can jeopardise not only current health but also future health and achievements; addressing young people's mental-health needs is vital to enable them to fulfil their potential (Patel et al., 2007). It is therefore essential that young people have timely access to appropriate

and effective treatment (National Institute for Health and Clinical Excellence, 2005). Despite this, many young people in the UK do not receive treatment for their depressive symptoms (Department of Health, 2011a). In a nationally representative epidemiological study of childhood psychiatric disorder, involving 10,438 children aged 5 to 15 years old, 929 were found to have a psychiatric disorder (Ford et al., 2003). When nearly 600 of these families were followed up at 18-months, in order to assess their service usage, approximately half of these young people had not been in contact with any services and only a fifth had been in contact with specialist mental health services (Ford et al., 2003).

Treatments for depression in children and young people

Young people with depression are often treated in Child and Adolescent Mental Health Services (CAMHS), which are specialist multidisciplinary teams who provide skilled assessment and treatment for children, young people and their parents/carers (Edwards et al., 2008). Child and Adolescent Mental Health Services in the UK are generally structured using a four-tier system (see Table 1).

Table 1: Description of the CAMHS four-tier system of organisation (adapted from Kitchen et al., 2017)

Tier	Description
Tier 1	Staff in Tier 1 are not mental health specialists (they tend to be GPs, nurses etc.). They offer general advice and treatment for less severe mental health problems, mental health promotion and identification of problems that are early in development. Where required, they refer patients to more specialist services.
Tier 2	Tier 2 are CAMHS specialists working in community and primary care settings who provide assessment and treatment to patients experiencing mental health difficulties, training to practitioners in Tier 1 and outreach to identify severe or complex needs requiring more specialist interventions.
Tier 3	Tier 3 are multidisciplinary teams working in the community, providing a

	specialised service for patients with more severe, complex and/or persistent disorders.
Tier 4	Tier 4 provides services for patients with the most serious difficulties and includes highly specialised outpatient teams, day or inpatient units.

Most mental health disorders emerge during childhood and adolescence; therefore, this time-period represents an ideal opportunity for early intervention before symptoms become entrenched in later life (Patel et al., 2007). The National Institute for Health and Clinical Excellence (NICE) guidelines provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness (National Institute for Health and Clinical Excellence, 2005). Clinical Guideline 28 (2005) relates specifically to the treatment of depression in children and young people aged 5 to 18 years. In this guideline, NICE stresses the need for access to evidence-based psychotherapies as a first line treatment for depression in children and young people (National Institute for Health and Clinical Excellence, 2005). The term psychotherapy refers to a collection of non-medical interventions designed to reduce psychological distress and maladaptive behaviour, or increase deficient adaptive behaviour, through counselling, interaction, training or treatment (Weisz et al., 2005).

Efficacious treatment options do exist for young people with depression. A large, well-conducted meta-analysis of 35 treatment outcome studies (Weisz et al., 2006) reported the mean effect of psychotherapy was moderate (Cohen's d of 0.34) indicating a small to medium treatment effect. The reliable treatment effects proved only durable in the relatively short term; effect sizes at one-year follow-up and beyond showed treatment effects were not maintained. However, despite the positive treatment effect observed, the authors suggest the modest improvements

reported are not as large as those described for other youth disorders (Weisz et al., 2006). This suggests renewed focus upon psychotherapies for depression in young people is timely. Furthermore, the literature review conducted as part of the meta-analysis above (Weisz et al., 2006) identified variability in treatment effect across the differing approaches to depression care. Of the 44 studies included in the review, 33 focused on cognitive change (i.e. Cognitive Behavioural Therapy [CBT] or other cognitive approaches) indicating the pervasiveness of this approach to treatment (Weisz et al., 2006). The meta-analysis included both published and non-published studies and did not find evidence of publication bias in the literature.

A notable US-based Randomised Controlled Trial (RCT), the Treatment for Adolescents with Depression Study (TADS) evaluated the short and long-term effectiveness of Fluoxetine (Selective Serotonin Reuptake Inhibitor [SSRI] medication), CBT and 'combined treatment' that included CBT plus Fluoxetine (as well as a fourth comparator, a pill placebo, in the short-term) in 439 adolescents with mostly moderate to severe MDD (March et al., 2007). Short-term outcomes at 12 weeks showed Fluoxetine and combined therapy were more efficacious than both CBT alone or a placebo. However, clinically meaningful improvement was seen in all three active conditions, indicating that a variety of treatment options can help to improve young people's symptoms of depression. A minority of patients in the TADS study retained clinically important symptoms of suicidal ideation and, crucially, these symptoms were significantly more common in patients who received Fluoxetine alone rather than those who received CBT or combined treatment. Patients receiving Fluoxetine alone were twice as likely as those receiving combined or CBT treatment to experience a suicidal event, indicating that CBT is a protective factor. The

conclusion from the authors of this large trial was that combination therapy should be the preferred treatment option for adolescent depression.

These results support the assertion that there is a role for psychotherapy in the treatment of depression in young people. However, a UK-based RCT of 208 adolescents (aged 11-17 years old) found no clinical or cost-benefit to the addition of CBT to treatment with SSRIs for moderate to severely depressed CAMHS patients who were non-responsive to a brief psychosocial intervention (Goodyer et al., 2007). Prior to randomisation, many young people responded positively to the simple, brief psychosocial intervention that was offered and the authors suggest this component should be explored further.

More recently, the Improving Mood with Psychoanalytic and Cognitive Therapies (IMPACT) study investigated three different approaches to treating adolescent depression in a UK context: short-term psychoanalytic psychotherapy, CBT and a brief psychosocial intervention (Goodyer et al., 2017). This RCT included 465 adolescents (aged 11 to 17 years old) with a diagnosis of moderate to severe MDD, who were followed up for a year following treatment. At the end of the study follow-up period 70% of the sample, from across all treatment arms, had improved substantially. The IMPACT study demonstrates that all three treatments can be delivered in UK CAMHS with equal confidence. This is noteworthy because it indicates there was no evidence of superiority of CBT (delivered over 28 weeks) or short-term psychoanalytical therapy (delivered over 20 weeks), compared with the brief psychosocial intervention (delivered over 12 weeks), in maintenance of reduced depressive symptoms at one-year follow-up. The authors conclude that future research should focus on whether or not brief psychotherapies are of use in

community or primary care settings. Although, this study does not answer questions relating to long-term effectiveness. It is clear that psychotherapeutic treatment for young people can reduce the impact of the symptoms of depression but it remains to be seen which of the briefer treatment approaches are most efficacious in this respect. For progress in finding effective treatments for young people with depression to be maintained, competing treatments need to be assessed and compared in the most rigorous manner available (Everitt and Wessely, 2008).

Rationale for behavioural activation treatment

The majority of the evidence-based treatments for youth depression require practitioners to attend lengthy and costly training courses. Cognitive Behavioural Therapy is the most investigated of these evidence-based treatments. Although CBT is recommended by NICE for the treatment of depression in children and young people (National Institute for Health and Clinical Excellence, 2005), access for patients is often limited by the availability of trained professionals (Pass et al., 2017). The extensive training requirements and cost of employing more experienced staff have been a barrier to CAMHS teams providing such training for their staff members (Edwards et al., 2008, Pass et al., 2017). The Improving Access to Psychological Therapies (IAPT) initiative has sought to improve this situation, firstly for adults and then for young people. The Child and Young People's IAPT (CYP IAPT) project was developed to improve the quality and provision of therapy for depression and anxiety in CAMHS from 2013 onwards (Department of Health, 2011a, b).

Patel, Flisher, Hetrick and McGorry (2007) suggest that the key problems within mental health services are the shortage of mental health professionals and the low capacity of non-specialist mental-health professionals to provide quality

services to young people. One treatment regularly used by adult IAPT to address these challenges is BA. The CYP IAPT programme focuses on building collaborative relationships with children, young people and their parents/carers, and encourages clients to identify and work towards their own goals and seek improvements in symptoms and functioning (Department of Health, 2013a). From the perspective of service delivery, BA may meet the need for therapies that can be provided by less experienced staff (Pass et al., 2017). The reason it may be well-suited for dissemination to non-specialists is due to the simplicity of the BA approach, which means that it is easier to teach practitioners and more straightforward to administer than traditional, more complex, psychotherapies (Jacobson et al., 1996, Jacobson and Gortner, 2000, Davidson et al., 2014, Richards et al., 2016). Behavioural Activation, as a more parsimonious alternative to full CBT, requires fewer treatment sessions and a shorter duration of practitioner training: as the "law" of parsimony (also known as 'Occam's Razor') suggests, among competing proposals it is the one with the fewest assumptions that should be selected. As a result, selecting BA as a treatment could assist increasing service capacity for psychological therapies in line with the CYP IAPT initiative. As an additional advantage, therefore, it is hypothesised that BA treatment could lead to cost-savings in CAMHS over traditional psychotherapies, as has been demonstrated in adult services (Ekers et al., 2011a, Richards et al., 2016). This is important in a context where services are required to become increasingly clinically and cost effective (Edwards et al., 2008).

There are important limitations to current psychotherapeutic treatments for depression in young people (McCauley et al., 2011). The previously mentioned meta-analysis of youth psychotherapy trials (Weisz et al., 2006) found CBT produced more

modest effects on depressive symptoms in children and adolescents, than in similar trials of adults. This finding suggests that young people and adults may engage differently with psychotherapy, thereby leading to differing treatment outcomes. Some commentators have suggested that the limited success of CBT trials in young people may be due to the level of cognitive sophistication required to utilise CBT fully (Ritschel et al., 2016, McCauley et al., 2011). In comparison, BA has been proposed as a less cognitively demanding alternative, which may therefore be better suited to young people (McCauley et al., 2011). The action orientated aims and simplicity of a BA approach may be developmentally appropriate for children and adolescents (McCauley et al., 2011). The findings of the meta-analysis also indicated studies utilising 'non-cognitive' treatments (such as behavioural approaches) demonstrated effects that were at least as robust as the cognitive treatments (Weisz et al., 2006). The authors conclude this may provide evidence that the most beneficial treatments for youth depression may not need to focus on altering cognitions.

Research has further indicated that treatment duration is not correlated with outcome (Weisz et al., 2006, Goodyer et al., 2017), suggesting briefer treatments, such as BA, have the potential to be as effective as longer ones in young people. Moreover, the TADS study reported that half of their sample did not respond to CBT treatment at 12 weeks (short term follow-up) but, by week 18, 65% had responded (March et al., 2007). Previous commentators have noted this suggests treatment effects may be dependent upon receiving an adequate 'dose' (of nine or more sessions) and the treatment effects are not likely to be apparent for several months following treatment. This is particularly problematic in youth populations who are

prone to treatment drop-out (McCauley et al., 2011); in adolescent outpatient populations drop-out rates were found to range between approximately 16-75% (De Haan et al., 2013). The high number of CBT sessions required, coupled with the likelihood of treatment drop-out in this population, demonstrates a need for psychotherapies of a briefer duration, where improvement is seen earlier in the course of treatment. Generally, in BA treatment, the BA model is covered during the first or second treatment session meaning that gains can be seen early on during treatment (Ritschel et al., 2016).

In light of the limitations of current treatments for depression and the inherent developmental factors present in a child and adolescent population, it is timely to explore novel treatment approaches that challenge the prominent cognitive paradigm, in order to extend treatment options for depression. It is CBT that is the current dominant treatment for depression, but owing to the limitations detailed above and the potential for BA to challenge some of these restrictions, this thesis considers BA as a plausible treatment option for young people with depression, which could potentially be deployed through CYP IAPT.

Behavioural Theory

Both the 2000 and 2008 editions of the Medical Research Council (MRC) framework for developing and evaluating complex interventions highlight the importance of a theoretical basis for interventions (Medical Research Council, 2000, Craig et al., 2008). The roots of the treatment we now know as BA were established in a movement called behaviourism that began to influence Psychology in the early twentieth century, when behaviourists demonstrated that an individual's behaviour could be influenced by changing the events immediately preceding it (Rutter et al.,

2008). In 1952, Hans Eysenck coined the term 'behaviour therapy' to refer to the application of behavioural principles to the treatment of patients (Rutter et al., 2008). Behavioural Activation is one such treatment. In 1976, Lewinsohn, Biglan and Zeiss published a BA treatment manual based upon the behavioural theory that depression is the result of low rates of positive reinforcement and inadequate social skills (cited in Kanter et al., 2010). Following this, behavioural treatments fell out of favour, replaced by cognitive treatments (Kanter et al., 2010). Interest in BA as a treatment for depression was revived following a component analysis of cognitive therapy, which showed most of the improvement in depressive symptoms could be accounted for by the behavioural, rather than the cognitive, components of CBT (Jacobson et al., 1996). Since then behavioural therapies have been refined and more recently have experienced renewed attention.

Behavioural Activation is a collaborative, structured, time-limited psychotherapy informed by behaviour theory and is based on B. F. Skinner's concept of operant conditioning (Kanter et al., 2009, Rutter et al., 2008). Skinner proposed that most behaviour occurs spontaneously and is often followed by a reward or punishment. These experiences dictate the form and frequency of future behaviour patterns. Accordingly, BA focuses on understanding the patient's antecedent stimuli and consequent responses rather than the person's "inner" motives (Rutter et al., 2008). This is in clear contrast to cognitive psychological therapies such as CBT, which aim to modify the inner world of the individual (Rutter et al., 2008). The theory of causation also differs fundamentally: behaviour theory does not focus upon the reasons why a problem has arisen; instead, the focus is on the contingencies that maintain it (Rutter et al., 2008). A behavioural approach to

treatment ensures these external components are challenged with the patient, which leads to the learning of new, more helpful behaviours. In contrast, cognitive therapies often formulate inner turmoil as the result of incompatible beliefs and desires and the process of making these beliefs explicit leads to the resolution of such conflicts (Rutter et al., 2008).

Behavioural Activation theory proposes that when positive reinforcement is lost from a person's environment, depression results (Kanter et al., 2009). Depression is subsequently maintained through a cycle of avoidance of usual activities that, over time, leads to reduced contact with sources of positive reinforcement (Kanter et al., 2009). The introduction of BA therapy aims to break this cycle by increasing time spent in pleasurable or 'healthy' activities, thus increasing the opportunities for contact with stable sources of positive reinforcement, which in turn may improve functioning and mood (Kanter et al., 2009, Davidson et al., 2014). Behavioural Activation focuses on the associations between the patient and their environment, as well as triggers and maladaptive coping strategies, which result in the cause and maintenance of depression (Hopko et al., 2003).

The postulated method of change is therefore also different; traditional psychotherapies rely on an unconscious process whereas behavioural therapy demands active involvement in challenging maladaptive behaviours (Rutter et al., 2008). In behavioural therapy, problems are defined as measurable, externally observable events in contrast to more general concerns that may be formulated in other psychotherapies (Rutter et al., 2008). A review of the component parts of BA interventions identified eight overarching commonalities (Kanter et al., 2010).

Although different versions of, or approaches to, BA exist, a central tenet that all share is monitoring a patient's activities, a component called 'activity scheduling' (Kanter et al., 2009, Kanter et al., 2010). Activity scheduling helps the client to engage in their environment to reduce avoidance (which can be a barrier to partaking in behaviour that could be positively reinforcing) in order to lay the foundations to increase positive reinforcement in their lives (McCauley et al., 2016). Most of these activities are completed outside of the BA formal treatment sessions (Davidson et al., 2014). Activities have to be practical and achievable and more complex goals are required to be broken down into manageable steps (Davidson et al., 2014). Other component BA techniques or strategies include assessment of life goals or values, skills training/relaxation, contingency management, procedures targeting verbal behaviour or avoidance (Kanter et al., 2010).

Behavioural Activation in adults

Behavioural Activation is recommended as a treatment for depression in adults by NICE and is routinely provided by adult IAPT services (National Institute for Health and Clinical Excellence, 2009b). This is indicative of the strong evidence base for the treatment of adult populations using a BA approach.

A systematic review and meta-analysis identified 12 studies (incorporating 476 people) where BA was compared to CBT in adults. There were no statistically significant differences between groups found in post-treatment depression symptom level or at follow up (Ekers et al., 2008). The parsimony argument mentioned previously as the foundation of the rationale for BA, is further strengthened by the results of another RCT of a BA intervention in adults (Ekers et al., 2011b), which demonstrated that BA could be delivered effectively by generic mental health

workers who had no previous psychotherapies training. In this context, BA has been found to be more cost-effective than usual care in adults with depression (Ekers et al., 2011a). A more recent meta-analysis of BA for depression in adults, updated the earlier manuscript from 2008 (Ekers et al., 2014). It considered BA versus control conditions or anti-depressant medication, identifying 26 RCTs including 1524 participants. Most BA interventions were found to be individual or group-based, although two studies used a self-help approach. The results were comparable across different therapy formats or approaches. The meta-analysis compared BA for depression to a control treatment in 25 of these studies (including 31 comparisons) for 1088 participants. The meta-analysis of depression symptom level post-treatment showed BA to be superior to the controls (SMD -0.74 [95% CI -0.91 to -0.56]) indicating a large effect size in favour of BA (see Figure 2). Interestingly, in a sub-group analysis, three of the included studies used non-specialists to provide treatment and the effect sizes remained large (when compared to treatment delivered by specialists). These studies were of good quality, representing further support for the utility of dissemination of BA by non-specialists. Similarly, the authors explored whether the complexity of the BA intervention influenced the treatment effect sizes but found no association. The impact of the number of treatment sessions was also explored (median number was eight sessions) but this was not found to be associated with effect size. Again, this bolsters the parsimony argument, in that a simple, brief treatment is preferable over a more complex alternative such as CBT. Behavioural Activation was also compared to medication; four studies, including 283 participants, were identified but two were removed from the analysis due to poor quality metrics. The analysis found a non-significant effect

size in favour of BA (SMD -0.38 [95% CI -1.23 to 0.47]). The authors noted that the study quality was low in most studies and there was no evidence of publication bias.

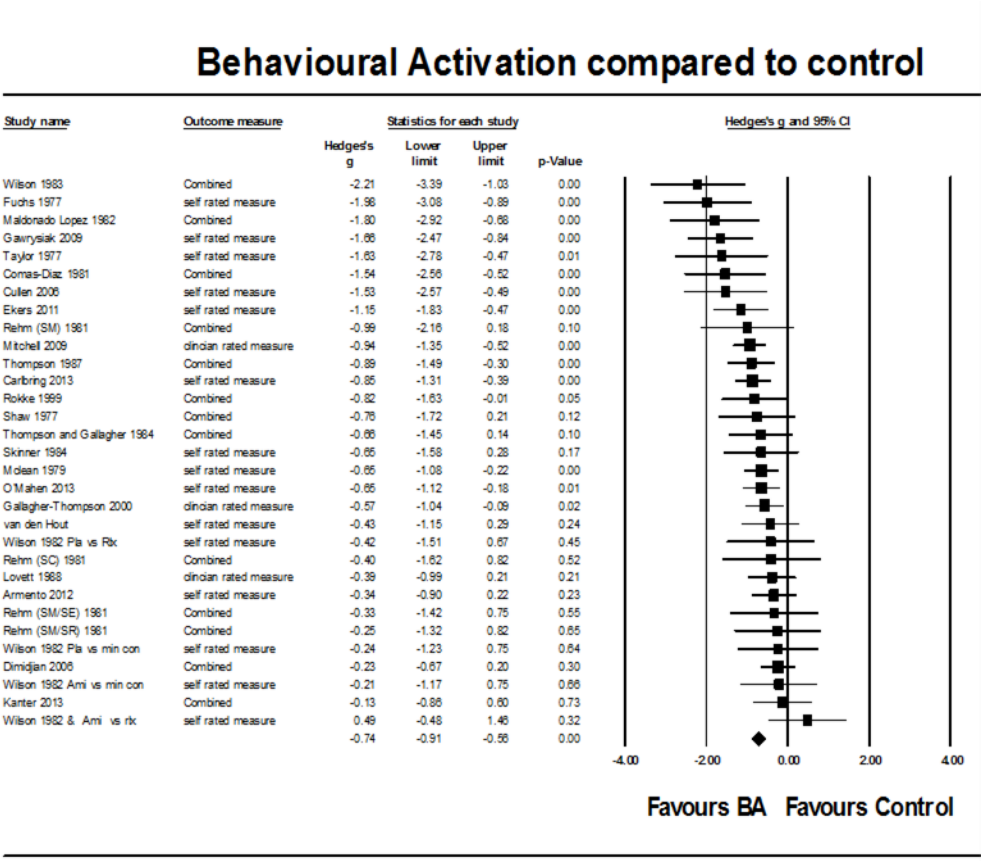


Figure 2: Reproduced with permission from Ekers et al., (2014), BA vs. control post-treatment (ordered by effect size, high to low)

More recently, BA has been compared to CBT in a large RCT (the COBRA study) of 440 adults with MDD to establish the clinical efficacy and cost-effectiveness of the treatments (Richards et al., 2016). The COBRA study found BA delivered by junior mental health workers (with less intensive and costly training) was not inferior to CBT delivered by more experienced therapists in reducing patient's depressive symptoms. Alongside this, BA was found to be more cost-effective than CBT, which was attributed to the cost saving associated with using staff with no professional

training in psychological therapies. This is the largest trial of BA to date and the results suggest BA is a viable treatment for depression that compares favourably to CBT treatment.

Behavioural Activation in children and young people

Compared to the ubiquity of research surrounding BA treatment for depression in adults, there is considerably less BA research focusing on young people. Despite this, a number of adaptions have been suggested to BA in order for it to be delivered to children and adolescents, rather than adults. In Figure 3 and Table 2, the current evidence base for BA treatment for depression in children and young people has been presented in the form of an evidence hierarchy. Studies focusing on depression prevention have not been included. An evidence hierarchy is a framework for ranking evidence, that assists the reader in assessing the effectiveness of interventions based upon the quality of the research design used (Akobeng, 2005a, b). Although different pyramid designs exist (Murad et al., 2016), the central premise is the same, the pyramid indicates which studies should be given more weight where different study designs have been used to examine the same questions (Akobeng, 2005b). Simple observational methods are illustrated at the bottom of the pyramid through to increasingly rigorous methodologies at the top; as the pyramid tapers so does the inherent risk of bias (Akobeng, 2005b). Evidence hierarchies can be used to guide health care professionals to make clinical decisions on the best available research evidence in tandem with their clinical expertise and patient values. This concept is known as evidence-based medicine or evidence based practice, the aim of which is to provide optimal patient care (Webber, 2014, Akobeng, 2005a). The evidence-based practice model suggests practitioners should accord greater weight

to evidence higher in the evidentiary hierarchy, such as systematic reviews or RCTs, as these studies have better internal validity (Webber, 2014). Internal validity is the extent to which it is free from bias (Higgins et al., 2011). Initial studies investigating the potential for BA to be utilised in children and adolescents have had some success. However, the vast majority of this evidence comprises of small, non-randomised studies, case series or case studies. In the absence of other higher quality evidence, all forms of evidence should be considered (Webber, 2014). The following section details the current available evidence for BA for young people with depression.

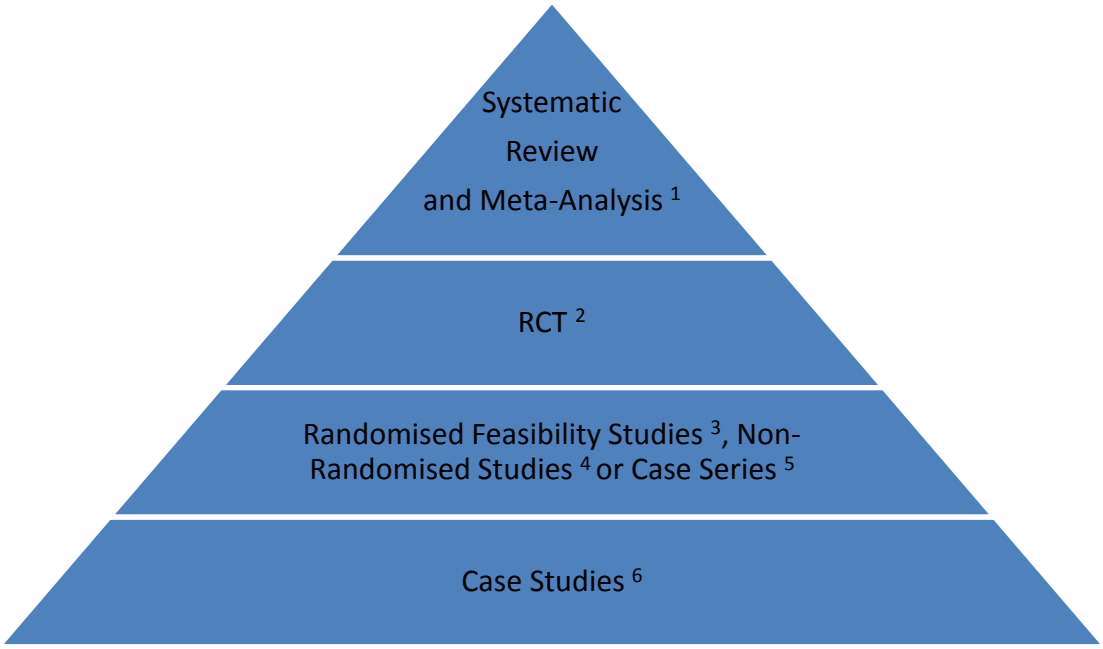


Figure 3: Evidence hierarchy illustrating the current evidence for BA treatment in children and young people* (see Table 2)

Table 2: Author, year and study title of research illustrated in Figure 3

	Position in the evidence hierarchy	Study Authors	Year	Study Title
*	Not included: lack of clarity over study design	Davidson, et al.	2014	Feasibility assessment of a brief, web-based behavioural activation intervention for adolescents with depressed mood.
1	Systematic Review	Tindall, et al.	2017	Is behavioural activation effective in the treatment of depression in young people? A systematic review and meta-analysis.
2	RCT	Weersing, et al.	2017	Brief behavioral therapy for pediatric anxiety and depression in primary care: A randomized clinical trial.
		Chu, et al.	2016	Transdiagnostic group behavioural activation and exposure therapy for youth anxiety and depression: Initial randomized controlled trial.
		McCauley, et al.	2016	The adolescent behavioural activation program: Adapting behavioural activation as a treatment for depression in adolescence.
		Stark	1985 (Unpublished)	A comparison of the relative efficacy of self-control therapy and behaviour therapy for the reduction of depression in children.
3	Randomised Feasibility Studies	Riley & Gaynor	2014	Identifying mechanisms of change: Utilising single-participants methodology to better understand behaviour therapy for child depression.
		Douleh	2013	Motivational interviewing assessment and behaviour therapy as a stepped care approach to the treatment of adolescent depression.
		Arnott, et al.	2012 (Unpublished)	Body and mind: An evaluation study of the effectiveness of a brief intervention in obese and depressed youth.
4	Non-Randomised Studies	Ritschel, et al.	2016	Behavioral activation for major depression in adolescents: results from a pilot study.
		Wallis, et	2012	Behavioural activation for the treatment of rural adolescents with depression.

		al.		
		Ritschel, et al.	2011	Behavioural activation for depressed teens: A pilot study.
		Chu, et al.	2009	An initial description and pilot of group behavioral activation therapy for anxious and depressed youth.
5	Case Series	Jacob, et al.	2013	Behavioural activation for the treatment of low-income, African American adolescents with major depressive disorder: a case series.
		Tiffin, et al.	2012 (Unpublished)	Behavioural activation in young people- A feasibility study.
		Weersing, et al.	2008	Brief behavioral therapy for pediatric anxiety and depression: Piloting an integrated treatment approach.
		Gaynor & Harris	2008	Single-participant assessment of treatment mediators: strategy description and examples from a behavioural activation intervention for depressed adolescents.
6	Case Studies	Pass, et al.	2017	Brief behavioral activation treatment for depressed adolescents delivered by nonspecialist clinicians: A case illustration.
		Pass, et al.	2016	Brief behavioural activation for adolescent depression: Working with complexity and risk.
		Pass, et al.	2015	Adapting brief behavioural activation (BA) for adolescent depression: a case example.
		Ruggiero, et al.	2005	Application of behavioral activation treatment for depression to an adolescent with a history of child maltreatment.
		McCauley, et al.	2011	Expanding behavioural activation to depressed adolescents: Lessons learned in treatment development.

Early Investigations of behavioural activation for young people with depression

The first published case study of BA with an adolescent was in 2005 in the USA, where BA was applied to treat mild depression in a 17 year old female with a history of maltreatment; the results indicated positive treatment outcomes for the patient (Ruggiero et al., 2005). The 8-session intervention was based upon BA for Depression (BATD), which was established around the principle that depression is the result of reduced reinforcement for non-depressive healthy behaviours and increased reinforcement for unhealthy depressive behaviours (Kanter et al., 2010). The aim of BATD is to re-address this balance by increasing healthy behaviours. This case study did not include follow-up beyond the eight BA treatment sessions nor had the patient received a diagnosis of depression at baseline. Case studies are usually presented at the bottom of an evidence hierarchy pyramid (Figure 3), because they are considered to be anecdotal evidence and, therefore not an adequate study design to explore treatment efficacy; many psychiatric disorders improve spontaneously, so on the basis of this evidence, we are unable to attribute the improvement to the treatment provided (Everitt and Wessely, 2008).

A series of these so-called anecdotes, known as a case series, can be criticised in the same manner. Data from four depressed adolescents who demonstrated remission following a BA intervention were used as individual cases to explore treatment mediators (Gaynor and Harris, 2008).[2] Ten adolescents (aged 12-18 years old) from US community settings were screened and a diagnostic interview was

[2] A treatment mediator is a variable that mediates the effect of treatment on an outcome where the event occurs during treatment, is correlated with treatment and explains all or part of the effect of treatment on the outcome measure (Gaynor and Harris, 2008).

completed to ascertain a DSM-IV diagnosis of major depression. Six met the inclusion criteria and two of these dropped out after the first treatment session. The intervention was 'Values Based BA', which included 12, one-hour sessions. All four participants who received treatment, reported positive change; BA increased activation (compared to behavioural disengagement) in the majority of cases and this was followed in half of cases by substantial reduction in depressive symptoms. For two of the young people, increased activation appeared to be a mediator, whereas decreased dysfunctional thinking did not emerge as a mediator.

Behavioural activation for comorbid depression and anxiety

A BA approach has been used for young people with both depression and anxiety symptoms. A US study explored the application of a primarily behavioural treatment to young people with comorbid anxiety and depression in primary care (Weersing et al., 2008). The authors term the treatment 'Integrated Brief Behavioural Therapy', which combines BA for depression and exposure therapy for anxiety. Although based in primary care, the staff who were trained to deliver the treatment had prior mental-health experience, which the authors note was not a typical resource in this setting. This study focused on the development of a brief treatment (8 sessions delivered over a 12-week period). The treatment was successfully applied to two young people (aged 13 and 17) who were followed up at 12 and 24 weeks.

Group BA therapy was the next format of treatment to be commented on in the published literature; it was piloted with five young people (aged 12 to 14 years old) with comorbid depression and anxiety (Chu et al., 2009). This small pilot study using a 13-week group BA intervention was implemented in a large public middle school in the USA (Chu et al., 2009). Two out of the five young people recruited had a

primary diagnosis of MDD: however, all participants experienced at least sub-clinical levels of both anxiety and depressive disorders (Chu et al., 2009). Potential participants were identified as likely to meet the study inclusion criteria by school counsellors. One limitation of the study design was that the treatment was delivered by two mental health specialists who were not a typical resource available to the school, which limits the transferability of the findings and hinders implementation on a larger scale. Nevertheless, there were high levels of uptake (75%) and high levels of completion (80%) of the intervention (Chu et al., 2009), although some attendance issues were evident. The results suggested that the majority of participants experienced moderate benefits and there was an overall trend in improvement of symptoms (Chu et al., 2009). Due to the small sample size, no inferences could be made regarding the efficiency of the therapy. The major weakness in this study was the lack of a control group.

In the USA, a case study documented the use of 'Individual Behavioural Activation Therapy' in a university based research clinic, with a 10 year old male, alongside exposure therapy for depression and anxiety (Chu et al., 2012). This case study echoed the earlier findings that BA may be a useful treatment option for young people experiencing mood and anxiety difficulties.

In a larger randomised study, Chu and colleagues allocated 35 young people (aged 12 to 14) to ten one-hour group BA sessions or a 15-week waiting list control (Chu et al., 2016). Young people were followed up at four months and improvements in activation and fewer negative thoughts were observed.

Small-scale investigations of behavioural activation for young people with depression

In another US-based study, McCauley and colleagues discuss the rationale for the application of BA to young people and the adaptation of the treatment following its unsuccessful application to a male 17 year old patient with MDD (McCauley et al., 2011). This patient dropped out after 10 treatment sessions and the BA approach did not help to improve the patient's depressive symptomology. The reasons for this were explored and the treatment was adapted in accordance with these findings.

Other small pilot studies in the USA, and in Australia, demonstrate that BA is feasible and acceptable in secondary care settings for young people with depression (Ritschel et al., 2011, Wallis et al., 2012). A small US-based study using a within-subject design found that six adolescents with a diagnosis of MDD who received a BA intervention showed significant improvements in depressive scores, with four participants no longer meeting the criteria for depression (Ritschel et al., 2011). Participants, aged 14 to 17, were offered a maximum of 22 sessions over 18 weeks at an outpatient adolescent mood clinic (Ritschel et al., 2011). However, the assessors responsible for collecting outcome data were not blinded to participants' diagnostic or treatment status, which is a source of potential bias. In addition, no follow-up data was collected on the adolescents who underwent the intervention.

In rural Australia, BA has been piloted as a treatment for depression for young people aged 13 to 18 years old, in a study which also used a within-subject design (Wallis et al., 2012). Participants were recruited through referrals from primary care to the local secondary care mental health service (Wallis et al., 2012). Five female adolescents, aged between 14 and 15 years old, experiencing mild to severe levels of depression, completed the 10-week BA programme (Wallis et al.,

2012). Again, the results appeared to be promising, with all five patients displaying reduced symptoms of depression after the treatment (from baseline to completion) (Wallis et al., 2012). Both of these studies were limited, in that they did not include a control condition, which means the improvements noted may be attributable to something other than the BA treatment.

A case series describing BA treatment for low-income, African American adolescents with depression also indicated it was feasible and acceptable (Jacob et al., 2013). Participants, aged 14 to 17, were recruited from a large urban hospital in the USA as part of standard clinic intake procedures and via flyers in community mental health clinics (Jacob et al., 2013). Potential participants were screened initially using a telephone interview, and a full diagnostic interview was completed for those who appeared eligible. Participants received between 14 and 17 BA therapy sessions. Clinician and patient ratings indicated that, in two out of the three cases reported on, patients no longer met the criteria for MDD (Jacob et al., 2013). However, due to study participants continuing medication alongside their BA treatment, it remains unclear as to whether it was the interaction between BA and medication that led to the reported improvements. Satisfaction ratings indicated that both patients and their parents/carers found the BA treatment acceptable (Jacob et al., 2013). Furthermore, the study team deemed BA to be a feasible treatment option in this context.

A web-based BA intervention for American adolescents was the subject of another feasibility study (Davidson et al., 2014). This was in the context of a website called Bounce Back Now, which is a resource for disaster-affected adolescents and their families who are at risk of post-disaster mental health problems. One of the

four modules on the website focused on low mood and included a brief BA intervention. Researchers video-recorded 24 adolescents aged 12-17 (recruited from psychiatric clinics) undertaking the computerised intervention (the depression module that included the BA) and encouraged the adolescents to voice their opinions aloud whilst working through the module. Although this initial scoping study included participants with a broad range of depressive symptoms, over 70% did not meet the clinical cut-off for depression on the measure they utilised and it was based on only one-session of the intervention. This initial study was designed to test the module's usability and received positive feedback but did not evaluate outcomes relating to mood. Bounce Back Now was subsequently evaluated in a population-based study of 2,000 families recruited from tornado-affected postcodes using an address-based sampling strategy. Participants were followed up at four and 12-months to assess the rates of uptake and completion. They found low rates of uptake with only 36% accessing the site but over 60% of these completed the BA module. Again, there was no investigation of outcomes relating to mood.

Behavioural activation for young people with depression in the UK

As found in other international work, feasibility research conducted in UK school and primary care settings by the Mental Health Research Centre (MHRC) at Durham University has demonstrated that BA therapy is acceptable to young people, their parents and clinicians (Arnott et al., 2012, Tiffin et al., 2012). The MHRC studies were the first to explore the feasibility of BA in a UK context. The two, as yet unpublished, studies of young people with depression, one in a school setting (with adolescents with comorbid weight problems) and one in primary care, also demonstrated BA therapy was acceptable to young people, their parents and clinicians, but feasibility

issues with treatment delivery were evident in both environments. The learning gained from these studies will be discussed further in Chapter 2.

Three further case studies indicated that delivery of BA would be feasible for young people in a UK CAMHS outpatient clinic (Pass et al., 2015, Pass et al., 2016, Pass et al., 2017). One case study focused on a 15-year-old female (Pass et al., 2015), whilst the other two were undertaken with 16-year-old females (Pass et al., 2016, Pass et al., 2017). All focused on adapting a brief BATD intervention for adolescents. However, as with much of the research conducted to date, they utilised a case study design, which limits any inferences that can be drawn from the evidence. Another UK-based study, which aims to assess the feasibility of integrating a BA approach into Tier 3 routine practice, has been registered but no results have yet been published (Health Research Authority, 2017).

Larger-scale investigations of behavioural activation for young people with depression

One study that has addressed many of the criticisms of previous work on the application of BA to young people with depression, is a large US study (McCauley et al., 2016). This RCT of 60 adolescents (aged 12 to 18 years old) with MDD, compared 14 sessions of BA (delivered over 12-weeks) to usual evidenced-based care (i.e. CBT or Interpersonal Therapy) in a university hospital-based community mental health clinic. As RCTs are considered to be the 'gold standard' for evaluating the effectiveness of interventions (Akobeng, 2005b), they are situated higher in the evidence hierarchy than other trial designs such as case studies or series. The trial results indicated both treatment conditions produced statistically significant improvements in depression, functioning, activation and avoidance. McCauley and

colleagues (2016) conclude that the results of the pilot RCT provide support for the feasibility and clinical importance of BA in the treatment of adolescents with depression.

Another US-based study evaluated BA treatment (maximum of 22 sessions) delivered to 28 adolescents, aged 14-17, with MDD over 18-weeks at an outpatient clinic (Ritschel et al., 2016). Participants were assessed using standardised outcome measures at baseline, midpoint and end of treatment and were followed up at three and six months. This study also collected qualitative data from semi-structured interviews following treatment. The authors conclude the results suggest BA is an effective treatment for adolescents with depression, as over 90% of those who completed treatment no longer met the criteria for MDD. There was also evidence these effects were maintained in the medium term. However, this study did not use a control condition and did not include all participants in their statistical analyses.

Systematic review and meta-analysis of behavioural activation for young people

Systematic reviews and meta-analyses are most often illustrated at the top of evidence-hierarchy pyramids, denoting the ability of this approach to synthesize the evidence. Systematic reviews can also be seen as a 'lens' through which evidence is viewed and appraised (Murad et al., 2016). As discussed at the start of this chapter, a systematic review exploring the effectiveness of BA as a treatment for depression in young people was undertaken at York University, which was published in 2017 (Tindall et al., 2017). The systematic review and meta-analysis reported reductions in depression scores following BA treatment (Tindall et al., 2017). The authors used the term 'BA' to encompass all therapies based upon a broad behavioural approach to

the treatment of depression regardless of the specific terms used to describe the intervention. At first glance this review might appear to present a convincing argument that BA is an effective treatment for depression in children and young people, but the authors identified methodological problems in the included studies and emphasised the lack of good quality research in this area (Tindall et al., 2017). Ten studies were included in the systematic review, although only three of these were suitable to be included in the meta-analysis. Previously mentioned studies (Pass et al., 2015, Davidson et al., 2014) and another study that looked at depression prevention in US college students aged 17 and over (Reynolds et al., 2011) were excluded due to the participants not having received a diagnosis of depression at baseline. The lack of diagnostic assessment is unsurprising, in light of the findings of the aforementioned earlier systematic review (Weisz et al., 2005) where the authors found half of youth psychotherapy studies did not include an adequate diagnosis at baseline (either not at all, or not using a reliable standardised tool). Furthermore, the trial that constitutes a large part of this thesis (which will be described in Chapter 4) was noted in the systematic review of the current BA literature but was excluded due to the study results being unavailable at the time of analysis. Only three RCTs were identified by the systematic search strategy used (McCauley et al., 2016, Chu et al., 2016, Stark, 1985), all three of which were in US populations. However, it was unclear how one of these studies (Chu et al., 2016) was identified as it did not appear to be available during the stated electronic search period, between July and August 2015. Another of the identified RCTs was derived from an unpublished doctoral thesis (Stark, 1985), which included a treatment the author termed behavior therapy, rather than the more specific BA. It was not made apparent,

therefore, how this research differed from much of the earlier behavioural work for young people with depression. The remaining seven studies all used within-participant designs (Weersing et al., 2008, Chu et al., 2009, Ritschel et al., 2011, Wallis et al., 2012, Jacob et al., 2013, Douleh, 2013, Riley and Gaynor, 2014) and suffered from sources of bias. Overall, 170 participants were included across the 10 studies, with participants ranging from 8 to 18 years old. When the RCT studies were combined within the meta-analysis, a statistically significant difference in Children's Depression Rating Scale- Revised (CDRS-R) scores from pre- to post-treatment was found in favour of BA (see Figure 4). The authors concluded that there is preliminary evidence that BA may be an effective treatment for depression in young people. Interestingly, reduced anxiety scores and increased quality of life were also observed. Not only were reductions in depression scores reported following BA interventions across studies, those from the RCTs demonstrated a greater improvement when compared to the controls. However, these findings need to be interpreted with caution; due to the inconsistencies noted in one of the included RCTs, the results may not be accurate. The clearest message from the first systematic review and meta-analysis in the area was the poor quality and reporting of research to date, with many of the studies lacking the detail required to determine bias.

Although all included studies, regardless of the methodology used, reported reductions in depression, this review (Tindall et al., 2017) did not include any evidence from a UK setting. As the MRC guidance cautions (Craig et al., 2008) systematic reviews of complex interventions can be problematic due to the difficulties of combining different variants of complex intervention packages of care

together. Despite the broad conceptualisation of BA and the systematic review of a wide variety of relevant databases, the search strategy used by Tindall and colleagues (2017) did not identify the full selection of literature described in this chapter. This could be due to the inclusion of the concept of activity monitoring (and associated terms) into the search, which may have constrained the search, raising the possibility that other relevant literature may have been missed. The rigorously conducted scoping review detailed in this chapter therefore compliments the systematic review findings and offers crucial insight into the diverse research conducted to date on this topic.

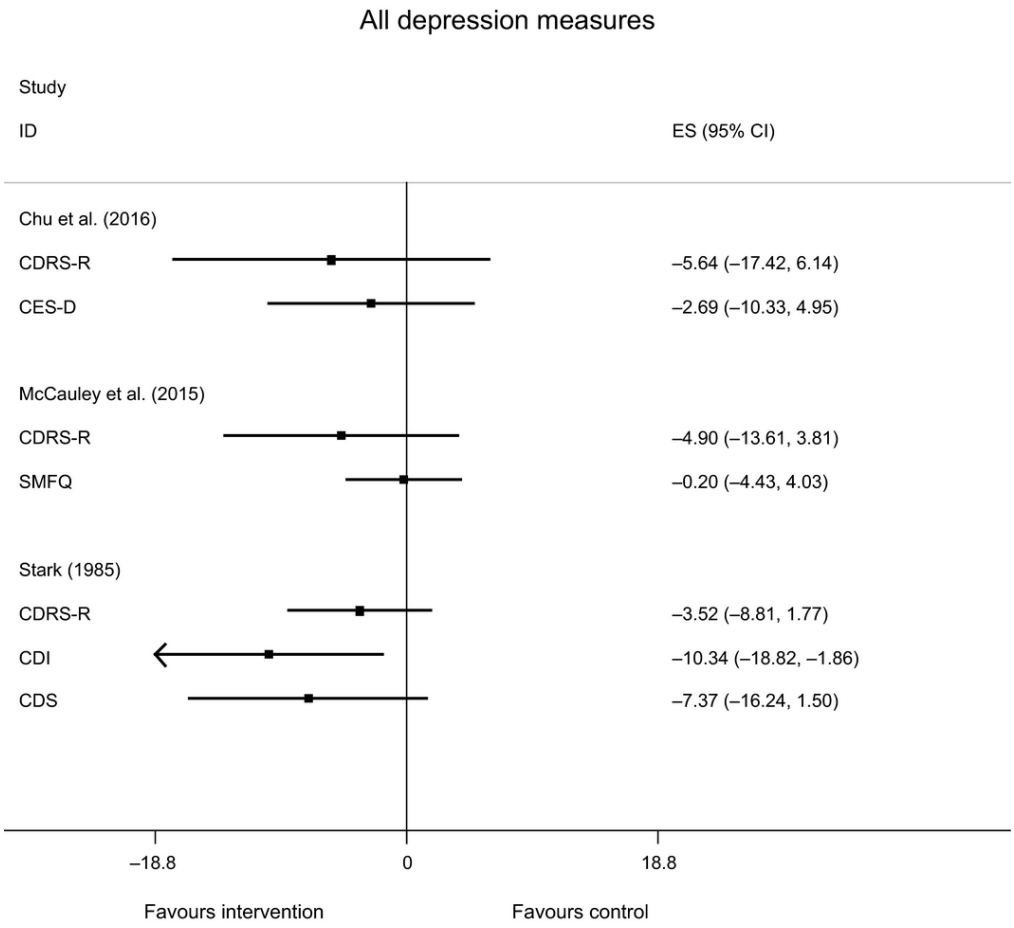


Figure 4: Reproduced with permission from Tindall et al. (2017), a forest plot of all depression measures across RCTs included in the meta-analysis

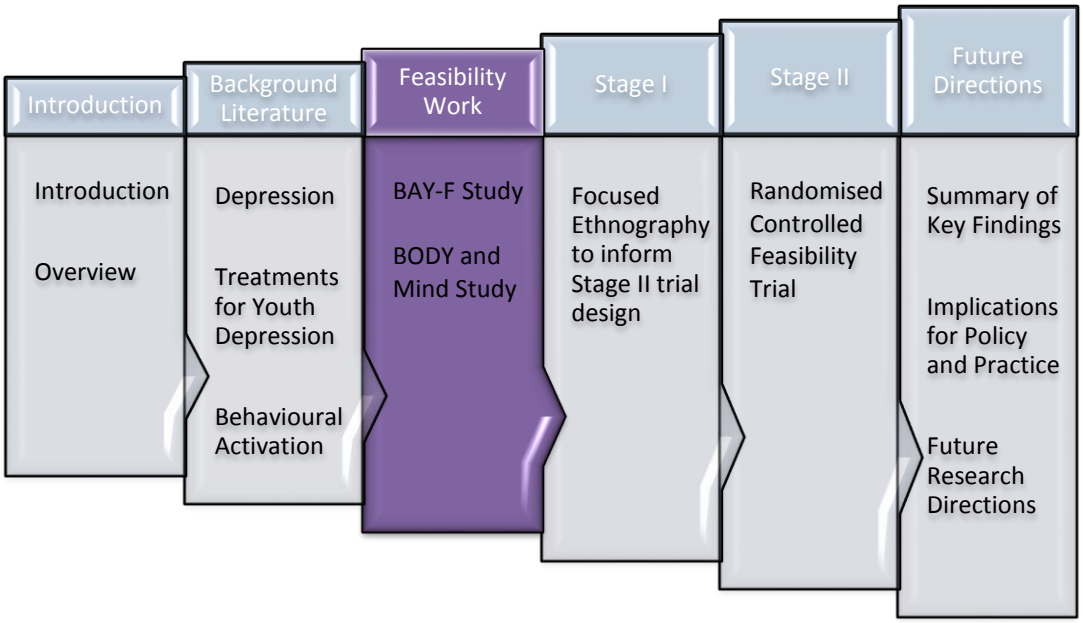
One large randomised study that was not included in the systematic review and meta-analysis by Tindall and colleagues (2017), is a trial by Weersing and colleagues (2017) that was only published following the review manuscript. A previously described approach to treating comorbid anxiety and depression in young people in primary care (Weersing et al., 2008) was investigated in a large RCT (Weersing et al., 2017). One hundred and eighty five young people (aged 8 to 16 years old) were randomised to brief behavioural therapy (8-12 sessions of BA plus exposure therapy) or assisted referral to care (personalised referral to outpatient mental health care plus telephone support). The results indicated that BA treatment is associated with benefits superior to assisted referral. One limitation of this trial is that participants did not have to meet full DSM MDD criteria to be offered study entry.

Observations from the background literature

Rutter (2008) notes that child psychotherapists face a similar but differing set of challenges from therapists working with adults; he cautions against assuming that adult therapy will automatically translate into an effective treatment with young people. Although this background literature review was not systematic in nature it has furthered the field by synthesising what is known from all study designs rather than limiting to RCTs. Despite growing empirical evidence, there remains a paucity of research on BA treatment for young people and more high-quality studies are needed. Particularly so in the UK, as much of the promising evidence to date has been conducted in a US setting where the composition of health services is different and driven by private medical insurance. The research that underpins this thesis was therefore conducted at an opportune time, with adolescent mental health being

high on the policy agenda and the need within the National Health Service to find innovative, sustainable ways to provide psychological therapy, effectively, to greater numbers of adolescents. Treatments also need to be responsive to the needs of clinical practice (Kessler and Glasgow, 2011). In the context of growing theoretical and empirical support, BA may well meet the need for a therapy that is effective, brief and able to be disseminated in a complex varied CAMHS context by a variety of clinicians.

Given the established need for further research on the delivery of BA to young people with depression in the UK, this thesis outlines the methods and findings of two studies (labelled Stage I and II) aiming to address this evidence gap. Relevant literature relating to the methodological approach used in each of these studies is presented at the beginning of each chapter and the results are situated in the context of the research presented above. The following chapter describes the unpublished feasibility work that was undertaken by myself and my colleagues at Durham University prior to this doctoral study, which had important implications for the work undertaken for this thesis.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Chapter 2 Feasibility Work

Introduction

The previous chapter considered the international and national evidence base for the use of Behavioural Activation (BA), as a treatment for depression in children and young people, across several settings. Three of these published accounts were single case studies undertaken in a UK Child and Adolescent Mental Health Service (CAMHS) setting (Pass et al., 2015, Pass et al., 2016, Pass et al., 2017). Further to these case studies, two additional studies (conducted by staff affiliated to the Mental Health Research Centre [MHRC] at Durham University) were highlighted that had been carried out in a UK general practice and secondary school setting (Arnott et al., 2012, Tiffin et al., 2012). As these two studies are unpublished, the following chapter discusses the findings of these feasibility studies, both of which aimed to assess the acceptability and feasibility of delivering BA as a treatment for depression in two distinct settings.

Although the inclusion of research completed as part of a study team prior to commencing a PhD is not traditionally included in a thesis, in this case, omission of the detailed findings of these studies would have led to difficulties in adequately situating the research conducted as part of this thesis. The topic of this PhD was initially conceived after my involvement in these projects at Durham University; I was involved in the data collection for both studies, which was completed alongside more senior colleagues prior to the start of my PhD. The rationale, design and results of these studies are summarised, alongside my personal reflections on the learning garnered from these experiences.

Behavioural Activation in Young People- A Feasibility Study in Primary Care (BAY-F)

Introduction and aim

Patient and public involvement (PPI) work with young people conducted prior to the BAY-F study indicated that BA would, in principle, be an acceptable treatment if delivered at GP surgeries. As a consequence, this small, within-subject feasibility study explored the acceptability and feasibility of using BA as an intervention for depression in young people delivered by Practice Nurses in a primary care setting. In the capacity of a Mental Health Support Administrator, I was responsible for the study implementation and adaptations to the treatment manual.

Method

Behavioural activation manual

The BA treatment manual was developed in the USA and had been piloted informally in 40 young people with depression (McCauley, 2011). The development of this 12-session manual, called 'Adolescents Taking Action' (ATA), has been detailed by McCauley and colleagues (McCauley et al., 2011); the initial sessions focus on introducing the BA model and individual conceptualisation of the model for the patient. Subsequent sessions focus on teaching the concepts that mood can be regulated by activity, guided activation, understanding mood versus goal directed behaviour, goal-setting and functional analysis. The ATA manual was anglicised for the BAY-F study and elements from a manual developed for a UK trial of BA in adults were also incorporated (Ekers et al., 2011b).

Clinician training

Two Nurse Practitioners were trained by a Tees, Esk and Wear Valleys (TEWV) National Health Service (NHS) Foundation Trust BA specialist via a five-day intensive

course. Practitioners were required to pass a competency assessment prior to delivering the therapy within the study. Both clinicians passed the competency assessment following the BA training. Clinician feedback indicated difficulties attending such lengthy training and suggestions were received that the training could be condensed into fewer days.

Recruitment

This study took place between January 2012 and April 2013. It was a non-randomised feasibility study with a before and after design. A brief depression screening procedure, the Patient Health Questionnaire- 2 Item Version (PHQ-2) (Kroenke et al., 2003) plus a supplementary help-seeking question, was offered to consecutive young patients (aged 12 to 18 years old) seen by two GP-based Nurse Practitioners in two GP practices in the North East of England. Adolescents who scored above the prescribed cut-off on the screening tool (indicating possible depression) and requested help for their symptoms were offered a structured diagnostic interview with a Consultant Psychiatrist using the Kiddie-SADS-Present and Lifetime Version (K-SADS-PL) affective disorders supplement (Kaufman et al., 1997). The K-SADS-PL includes the Children's Global Assessment Scale (CGAS), a measure of current functioning. Participants over the age of 16 were asked to provide informed consent to participate. Young people under 16 were asked to provide informed assent and parents were asked for informed consent for their young person to participate. Young people found to have Major Depressive Disorder (MDD) were offered a BA manualised intervention for approximately one hour per week, up to a maximum of 12 sessions (total number of sessions was at the therapist's discretion).

Data collection

Participants were assessed at baseline and end of treatment using the Mood and Feelings Questionnaire- Short Form (MFQ-SF) (Angold et al., 1995). Qualitative feedback was sought from Nurse Practitioners, participants and their parents, which was collated via ad hoc notes made by the study team.

Ethical approval for the study was granted by Durham University School of Medicine and Health Ethics Sub-Committee and the NHS National Research Ethics Service for County Durham and Tees Valley 2 Committee.

Results

Both Nurse Practitioners reported that most young people approached to participate in the study completed the screening questionnaire, although we were unable to ascertain specific recruitment figures due to imprecise record keeping by the Nurse Practitioners involved. In addition, the Nurse Practitioners acknowledged that the screen was not deployed to consecutive patients as intended. Despite these difficulties in administrating the screening tool, seven females aged 12 to 18 years old were identified as eligible to participate in the diagnostic interview, all of whom agreed to attend. All participants were recruited from one GP practice; screening at the other practice did not identify any eligible patients during the study period. All participants who attended the diagnostic interview met the study inclusion criteria (MDD on the K-SADS-PL) and agreed to take part in the BA intervention. Of the seven young people who were recruited, four participants completed all BA sessions, one with an accompanying parent. The remaining three participants stopped attending sessions after the first three treatment sessions. None of those who dropped out of

treatment were able to be contacted for follow-up. All young people who completed treatment reported lower MFQ-SF scores following treatment than at baseline.

Practitioner feedback suggested drop-out may have been largely due to improvements in participants' depressive symptoms. Similarly, in those young people who completed all BA sessions, the practitioner observed rapid improvements in depressive symptoms early on during treatment. The Nurse Practitioner reported difficulties in fitting the one-hour BA sessions into their usual 20-minute appointment slots. As a consequence, the practitioner completed some BA sessions outside of their regular working hours. Feedback from participants indicated difficulties in commuting to the GP practice, both in terms of time around their other commitments (i.e. college, school, social), and financially. Despite this, participants commented positively on the BA therapy content and the practitioner delivering it. The treatment was also considered acceptable by practitioners, but they identified a need for greater flexibility within the manual to better tailor the treatment to each young individual. The treatment manual was refined as a consequence of this feedback.

Reflections

The study design was pragmatic and naturalistic, with a simple before and after measure. The screening procedure was unable to be implemented as intended by Nurse Practitioners and the quality of data recording was poor. This limited our ability to estimate a potential recruitment rate. We found young people who completed the BA sessions experienced improvements in their depressive symptoms following treatment. Although practitioners attributed the high levels of drop-out to improvements in participants' depressive symptoms over the first few sessions, this

could not be verified because none of those who dropped out of treatment were able to be contacted to provide feedback. Similarly, in those young people who completed all BA sessions, depressive symptoms were reported to improve rapidly at the start of therapy, but this was not able to be formally captured as no interim measure of mood was taken. As a result, an additional measure of depression severity (MFQ-SF) was incorporated into the manual at baseline and weeks 4, 8 and 12, in order to retain a measure of depression severity in the event of participant drop-out. Although no formal qualitative methodology or methods were used to obtain feedback, informal feedback was useful to inform adaptions to the ATA manual. The layout of sessions was altered and additional optional topics incorporated, on the concepts of rumination and mindfulness, so the treatment could be better tailored to the individual.

Despite the discussed design concerns, it is still possible to observe feasibility issues relevant to my PhD research. Sessions were often carried out sporadically rather than via the intended weekly structure. The practitioner indicated that it was unfeasible to fit the lengthy one-hour appointments into their regular practice appointments of 20 minutes, meaning many sessions were completed in the staff member's own time. This would not be sustainable nor transferable outside of the BAY-F study. This also indicated to me that further involvement from the management team would be advisable, rather than relying wholly on practitioners themselves to make the necessary space in work schedules. Feedback from study participants indicated difficulties in commuting to the GP practice, which also suggests the need to consider alternative youth-friendly settings.

Key learning points

The screening procedure was acceptable to participants but burdensome to practitioners. The intervention itself was acceptable to young people and the practitioner, albeit this was a small feasibility study with no control condition involving only seven young people. There were also provisional indications that BA may be helpful in improving symptoms of depression in young people. Practitioners were able to be trained to deliver the intervention following minimal training, providing support for the view (from extant literature) that BA is easy to disseminate. However, it was not viable for the Nurse Practitioner to deliver such lengthy sessions as part of routine clinical practice and the setting caused access difficulties for many of the participating young people, which may have contributed to the high rates of drop-out observed. The conclusion of this feasibility study was therefore that alternative settings should be considered in which to deliver this acceptable and promising therapy.

BODY and mind study: A school-based feasibility trial of behavioural activation as a treatment for young people with comorbid weight and mood difficulties

Introduction and aim

Traditional obesity treatments have not addressed the underlying links between mood, coping and eating behaviours, which may explain why they have been largely ineffective (Ebbeling et al., 2002). In contrast, BA has been hypothesised to have the potential to address these fundamental links, and BA for comorbid obesity and depression has been previously explored in adult populations (Pagoto et al., 2008). The BODY and Mind study aimed to investigate the acceptability, practicality and

impact of a BA intervention for young people who were overweight or obese with symptoms of low mood or depression. In the capacity of a Research Associate (with no previous psychotherapies training), I was responsible for assisting in the school screening, delivery of the intervention and collection of the outcome measures, with the exception of the qualitative interviews. The results presented below have been written up for publication in an academic journal.

Method

Study design

This was a small, unblinded, mixed methods, feasibility Randomised Controlled Trial (RCT) with a waiting list control.

Recruitment

Data collection started in November 2012 and ended in March 2013. The study site, a school in the North East of England, was selected because students came from a diverse variety of backgrounds and ethnicities. In light of the findings from the BAY-F study, it was felt a secondary school setting may address some of the difficulties young people experienced in accessing their GP surgery.

All students in year groups 7 to 10 (aged 11-15 years old) were invited to participate in a systematic screening procedure. Pupils were provided with information on the study and those who wished to take part were asked to complete the PHQ-2 plus a supplementary help-seeking question during afternoon registration and were then weighed and measured to work out their Body Mass Index (BMI) in a private room. An alternative approach was used for year 7 pupils in light of their younger age; the information and questionnaire were sent home to parents/carers who were asked to complete the materials with their child. Children who scored

above the prescribed cut offs on both weight and mood measures were eligible for the next stage of the study, a diagnostic interview.

The consent procedure mirrored that used in the BAY-F study. Depression (MDD) or significant depressive symptoms (i.e., Depressive Disorder Not Otherwise Specified) were confirmed during the diagnostic interview using the affective disorders schedule from the K-SADS-PL administered by a Consultant Psychiatrist. Low mood was measured using the MFQ-SF, self-esteem with the Rosenberg Self-Esteem Measure (RSE) (Rosenberg, 1965), functioning with the CGAS and health and social functioning with the Health of the Nation Outcome Scales for Children and Adolescents (HoNOSCA) (Gowers et al., 1999).

Behavioural activation intervention

Young people were asked if they were happy to be randomly allocated to take part in the intervention straight away or to wait for 4-6 weeks prior to starting (waiting-list control). The BA intervention was then delivered for up to 12 sessions (total number of sessions was at the therapist's discretion). The study used training procedures and the BA manual adapted from the BAY-F study. Fidelity measures (ratings of audio recordings of treatment sessions) were completed to ensure treatment remained true to the BA model. Sessions were arranged after school hours or during school holidays at the on-site school sports centre. Parents were encouraged to participate.

Data collection

Young people were weighed/measured and completed the MFQ-SF, RSE, CGAS and HoNOSCA at regular intervals across the intervention period and at the end of treatment. Following treatment, participants and their parents were invited to

attend a semi-structured qualitative interview with an otherwise uninvolved researcher.

Ethical approval for the study was granted by Durham University Department of Psychology Ethics Advisory Sub-Committee.

Results

Recruitment

A total of 1126 pupils were invited to the initial screening (see Appendix 1 for a Consolidated Standards of Reporting Trials [CONSORT] diagram of the flow of participant identification and recruitment). Five hundred and fifty seven agreed to participate, giving a 49.5% consent rate (60% for years 8 to 10 and 19% for year 7). Of the participating pupils (n= 557), 33 scored above the prescribed cut off for both weight and mood giving an eligibility rate of 5.9%. Nine of the 33 pupils invited to the diagnostic interview agreed to attend. From the nine diagnostic interviewees, eight young people were eligible for the intervention (aged 13-15 years old). All young people who were asked agreed to be randomised. Four were allocated to each treatment arm (either BA or a waiting-list prior to BA).

Intervention

Participants completed between 8 and 11 sessions of BA, with seven out of eight young people completing all BA sessions prescribed by the therapist. Session attendance was high with only one participant missing their final session. However, some cancellations were rearranged due to ill health, missed appointments and transport difficulties, and two sessions were of necessity delivered in tandem, due to the families' other commitments (i.e., 8 BA sessions were delivered over 7 sessions).

A random 10% of sessions were rated for fidelity by the BA trainer and were deemed true to the BA model.

Qualitative interviews

Seven of the eight study participants agreed to take part in the qualitative follow-up interview; one participant was unable to be contacted (see Appendix 1 for examples of the identified themes).

The screening process was not viewed positively by the young people involved. School was viewed as a place of competing pressures and not an appropriate setting in which to ask sensitive questions relating to weight and mood. When asked about future study design, young people expressed a willingness to undergo randomisation to individual sessions of BA or other psychological therapies (or a waiting-list control for such treatments) but were less keen to be randomised to a medication treatment arm or to a group-based intervention. They reported high levels of satisfaction with BA session content, frequency and duration, as well as with the therapist. Most young people stated they would recommend the intervention to others experiencing similar difficulties, indicating the acceptability of the treatment to young people. Some young people reported significant and sustained improvements in mood and self-esteem.

In contrast, several barriers were highlighted by those young people who struggled to maintain the improvements observed during their treatment. The therapist and young people both stressed difficulties with scheduling appointments, particularly during school holidays, which resulted in significant breaks in the intervention delivery in the waiting-list group (which ran over the school holidays).

Parents reported that they had found the intervention highly acceptable, although parental difficulty in participating due to other commitments was highlighted as a feasibility issue. Parents were perceived as 'gatekeepers', who held the power to restrict or provide opportunities for the young person. Some parents were concerned that some manual worksheets were difficult to understand for young people. The feedback obtained from the study was used to adapt the materials and treatment accordingly.

Outcomes

Overall, from baseline to the end of treatment there was an effect size of 0.02 recorded for BMI. The effect-size for self-esteem (RSE scores) was 1.31 indicating a large effect. For depressive symptoms (MFQ-SF), the effect size was 0.76, again indicating a large effect. A MFQ-SF cut-off score of 7 or below indicates remission, which was achieved in five cases at the end of treatment (although one participant did not meet these criteria at baseline). In the remaining two cases, a decrease in MFQ-SF score was evident indicating improved mood not reaching the cut-off criteria. A large effect size was reported in current functioning (CGAS) of 1.71 and health and social functioning (HoNOSCA) of 1.55. These statistics exclude the one participant who was unavailable for the final planned treatment session. No significant events were recorded during or after the intervention and there was no evidence of any harms or unintended effects. As would be expected for BMI over such a short follow-up period, little change was observed. In contrast, notable improvements were seen in mood, self-esteem and functioning. However, due to the small sample size these results need to be interpreted with caution.

Reflections

Feasibility and acceptability issues were evident with the screening procedure. Large numbers of young people had to be screened to identify low numbers of eligible participants indicating mass screening was unfeasible. It would be more efficient to screen populations more at risk of depression, such as in secondary care. Further to this, few of those identified as potentially eligible accepted the invitation to a diagnostic interview. This suggested that the recruitment materials could be improved and may reflect the lack of PPI input prior to the start of the BODY and Mind study.

In contrast to the screening procedure, the BA intervention was judged to be both feasible and acceptable to young people, parents and the therapist. Low attrition rates further support the acceptability of the intervention. Despite being underpowered to detect significant change over the treatment duration, improvements in self-esteem, functioning and mood ratings were observed. There were no clear suggestions of improvements in BMI scores.

Treatment delivery in a school setting presented challenges. The inability to offer treatment sessions across school holidays or during school hours represented a barrier for young people and their parents, leading to gaps in treatment. The ability to offer more flexibility in the timing of treatment sessions would enable delivery of the treatment via the intended weekly format, and may facilitate greater parental involvement which seems likely to improve delivery of the treatment. Although parental components were included in the ATA manual, these were mainly delivered separately to the young person's treatment sessions. Parents acted as gatekeepers to resources and for this reason, integrating their involvement into their young

person's treatment sessions would enable greater collaboration. Overall, the adapted ATA manual and treatment approach was acceptable to young people, their parents and therapist, which was able to be delivered by a therapist with no previous psychotherapies training.

The participants were demographically representative of young people for the geographical area they were sampled from. As there were no study drop-outs, data were almost complete, with the exception of a missing set of outcome measures at the final session from one participant and a qualitative interview for a separate young person. Unlike in the BAY-F study, a formal qualitative evaluation element was included to explore young people's experience of the intervention, although this was limited by the lack of a formal method of analysis. As a single therapist was involved, it is not possible to generalize to other clinicians. However, the results suggest inexperienced therapists can be trained following a brief training course, indicating BA has the potential for dissemination to a wide variety of providers (i.e. teachers, support staff, youth workers).

Despite the positive outcomes reported, this investigation had some clear limitations. Firstly, although appropriate in a feasibility RCT, this study involved a very small number of children. Secondly, there was no long term follow up, which should be corrected in future trials. Thirdly, the waiting-list control period was short, which made it less likely that changes would be detected. The exploratory statistics are also underpowered to estimate effect sizes on the panel of outcome measures. In addition, no diagnostic interview was conducted following treatment so we do not know if the sample still met the criteria for a depressive disorder. Finally, no direct

measures of physical activity were included; future trials should incorporate such a tool.

Key learning points

This study is the first to explore the feasibility of BA as a treatment for comorbid low mood and overweight/obesity in young people. Mass school-based screening was costly and unacceptable, yielding low numbers of eligible pupils. This finding combined with the difficulties encountered with continuity over the school holidays, supports the use of settings other than schools to deliver treatment. In summary, these findings make a strong case for further exploration of the intervention. Our findings further suggest that the control condition should be one which young people would perceive as acceptable (such as an alternative psychotherapy).

Case study: a young person's account of receiving behavioural activation treatment

As well as reflecting upon the methodological strengths, weaknesses and learning gained from these studies, I was interested in understanding how young people had personally experienced BA as an intervention. One participant from the BODY and Mind study had already expressed a desire to support the University with future research projects and so, under the supervision of an experienced qualitative researcher, I conducted an interview with this young person, with the hope that their feedback would inform the design of future BA intervention trials and provide information that could be shared with future participants. A pseudonym[3] has been used to preserve anonymity and confidentiality.

[3] A pseudonym is a fictional name assigned to a person, group or place.

The interview had an opened-ended framework with no fixed question schedule. The young person was initially asked to describe whether they had found BA beneficial or problematic, with subsequent questions being modified in light of Dan's response.

When asked to reflect upon the benefits of BA treatment, Dan commented upon aspects of increased self-awareness of his mood. He highlighted how BA treatment had led to the development of a working relationship with the therapist and the improvement of existing connections with his family members:

> "It was a good experience but it's hard to describe. It helped you learn about yourself and how you cope with things emotionally. It was good to have a talk and establish a bond with your therapist/coach. This way you were more willing to share your personal information. It was good to talk as it felt like a chat at times. It made it a lot less formal and it made me feel more relaxed as sessions were flexible. If it had been more formal you would have been watching your words. It also helped how I interacted with my Dad, it sort of helped that out"

This excerpt shows the importance of flexibility in therapy, as well as the importance of a cathartic and supportive relationship with a therapist. Dan reported that the relaxed nature of the interactions was a facilitator for successful treatment.

Dan had his BA sessions once a week, for eight to ten weeks. This was, he said: "not too much, not too little. We did a lot of talking and completing worksheets but it was a good balance". But there were also less positive aspects to treatment:

> "It was a bit stressful at times, like having debates with my Dad why I was going for therapy. Also the homework/take-home tasks were a bit long sometimes, no one likes doing work I guess but it has to be done at the end of the day"

This highlights the challenging nature of BA, as established behaviours are questioned in order to explore and use alternative coping mechanisms. Along with this inevitably comes stress and hard work. Dan and I concluded that it would be

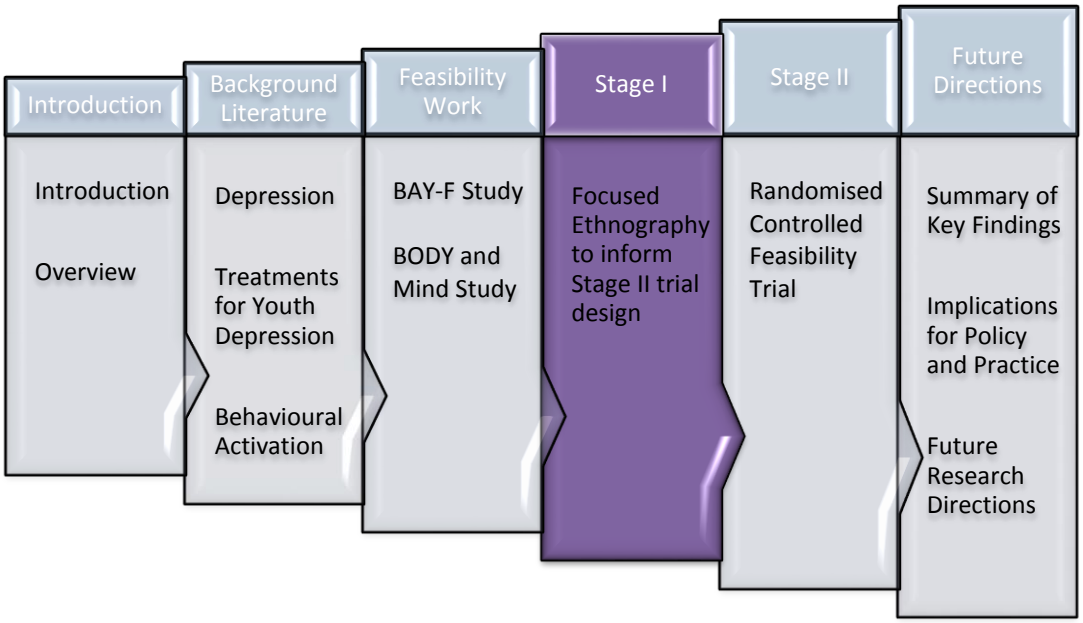
beneficial and important to highlight this in the information sheets of future studies providing BA treatment.

Finally, he was asked if he would recommend BA to other young people who were in a similar situation. He responded positively: “I would recommend it. It was a good experience. It didn’t feel like a therapy for depression”. These final endorsements help to explain why BA is so acceptable to young people; it is non-stigmatising and practical. This dialogue may be helpful when approaching young people to take part in such therapy. In particular, it may be important to inform young people that there may be elements of therapy that are stressful or time-consuming, but that these are necessary parts of BA that ultimately facilitate behavioural and mood related change.

Conclusions

Although all studies described above were conducted prior to my PhD, and in collaboration with other more senior members of MHRC staff, they are important in the narrative of this body of work. They have contributed towards my personal understandings of the potential utility of a BA approach for treating depression in children and young people, as well as adding to the sparse published literature currently available in the UK. Our feasibility work has made a strong case for further exploration of this promising treatment. The BAY-F study indicated the BA treatment was feasible but could not be delivered by Nurse Practitioners in primary care. The feasibility work in schools was acceptable and appeared feasible, however it was not a generalisable approach as the therapist was not a resource usually available in a school setting. Furthermore and perhaps most importantly, the therapist was

supervised by a BA expert and Consultant Psychiatrist who would not be accessible in a school setting. Without this support and risk supervision, delivery in a school setting would not be feasible. This influenced me to conduct my research in a CAMHS environment where those support and supervision structures would be in place, despite the plans of the research team to further explore the use of BA in school settings. The importance of adequate supervision of non-specialists delivering BA to young people has been reinforced in other applications of BA (Pass et al., 2017). However, whilst the CAMHS setting might appear to address many of the challenges experienced in school and primary care, it was a novel context in which to implement BA. Accordingly, some form of exploratory study was indicated. The following chapter discusses the first study conducted as part of my PhD research, a focused ethnography which served to explore CAMHS as a potential site for a planned trial of a BA intervention.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Chapter 3 Stage I: A Focused Ethnography of a Child and Adolescent Mental Health Service Site

The following study describes the focused ethnography that has been used to inform the design of Stage II of the research. This study was the consequence of initial site visits highlighting my lack of knowledge about the setting and in light of the need to make informed decisions in relation to the trial design. I will begin by discussing the aims, methodology and will then discuss how the findings led to alterations in the trial protocol of Stage II of this thesis.

Study background

Prior to the implementation of the trial around which this doctoral study was planned, site visits were organised with the respective Child and Adolescent Mental Health Service (CAMHS) Team Managers at two potential study sites. These site visits were an opportunity to acquire contextual knowledge of the CAMHS teams and the available site resources, to inform the trial protocol (now Stage II of the research). In fact, these visits only served to highlight the complex nature of CAMHS care for young people with depression, and it became clear to me that the breadth and depth of information required could not be obtained solely from such site visits. Settings such as CAMHS may be characterised as "complex systems", due to their multi-faceted, fluid and ever-changing context, with such environments being more similar to a dynamic ecology (Wells et al., 2012). Furthermore, the information that

was gained from the meetings with the Team Managers indicated that, without a greater understanding of the setting, the trial would meet insurmountable barriers and may be of limited relevance if the depression intervention was not able to account for the intricacies of clinical practice. This dictated the need for a more in-depth, longitudinal assessment of the study site, in order to understand these complexities fully and successfully design and implement a trial in this setting. Access to the site for the purposes of a pre-design stage of research was negotiated with one of the Team Managers, in exchange for me taking on a voluntary role within the CAMHS team whilst conducting the research. As a result, I was embedded into one of the CAMHS teams as an unpaid Assistant Psychologist for a two-year period (starting two months prior to the start of data collection for Stage I of the study in order to complete mandatory training). An ethnographic approach was selected as the most appropriate way to study and understand the setting.

Introduction and aims

Randomised Controlled Trials (RCTs) are generally considered to be the best way to measure the efficacy of clinical interventions (Stephenson and Imrie, 1998, Torgerson and Torgerson, 2008). However, the findings of such trials have often been criticised for their lack of applicability to real-world clinical practice (Savage, 2000, Kessler and Glasgow, 2011). This has been of particular concern for researchers evaluating complex interventions (Stephenson and Imrie, 1998, Wells et al., 2012), where an intervention may have been studied in a highly controlled research setting but has then encountered difficulties when implemented by clinical services. This has led to a move towards more 'pragmatic' trial designs that take

account of the intended setting (Stephenson and Imrie, 1998) and which aim to bridge the observed disparity between clinical research and clinical practice. The rigorous process of trial design needs to be informed by the clinical setting as this can improve quality and clinical relevance, as well as limit the waste of resources within the trial (Webber, 2014). This is all the more important, when considered in light of the fact that the evidence base for the National Institute for Health and Care Excellence (NICE) guidelines is principally developed from RCT evidence (Gould, 2010). A vital step in designing a pragmatic trial is to have an in-depth knowledge and understanding of the context into which the proposed trial is to be implemented. Context can be described as the setting in which an event, statement or idea occurs; it is not limited to the physical environment as it may also refer to anything that has an impact upon an individual's behaviour in that setting. Previous research has emphasised the impact of context upon the implementation of interventions, suggesting the need to account for this with local-level responses in the intervention setting (Wells et al., 2012, Lewis and Russell, 2013). As such, understanding the environment in which a trial will be conducted is critical to the successful implementation of the subsequent intervention.

Utilising the experience of professionals who have a good working knowledge of the study site has also been recommended as a way to inform research (Kendall, 2003). The utility of this approach has previously been demonstrated by Wells and colleagues (2012) who explored 'behind the scenes' in RCTs of complex interventions in order to understand the perceptions of staff and researchers towards the research being undertaken and how this may impact upon the implementation of the intervention. The application of staff expertise to inform planned research has been

referred to as “captured wisdom” (Webber, 2014). This phrase seems particularly fitting, as exploring staff views may provide insight into their experiences and knowledge of how the research findings can become better integrated into their working environment. Furthermore, the inclusion of clinicians’ views has been found to facilitate strategies that improve the efficacy of the trial itself (Turner-Halliday et al., 2014). Pragmatic trial designs that benefit from consultation with staff at the proposed study site may lead to well-designed trials that are more acceptable to staff. Currently there is limited literature available on how modern, multi-disciplinary, CAMHS teams engage with intervention trials, and it remains to be investigated how staff members feel about the proposed research and how these beliefs are played out in context. Although Kendall (2003) suggests early involvement of local research support units and fellow researchers to inform trial protocols, this would not meet the need I observed for in-depth, site-specific knowledge. Local research support units or researchers would be unlikely to have adequate knowledge of the subtle, nuanced behaviours that may affect decisions relating to trial design.

Another explanation for the reported chasm between research and practice is the limitations of traditional research designs (Barlow, 1981). Despite the identified need for more pragmatic trial designs and the recognised value of incorporating clinicians’ views into proposed research, there has been a lack of focus on methodologies to guide researchers in this endeavour. One suggestion has been to utilise a mixed methods approach by combining qualitative research components with a RCT design (Cresswell, 2009). The addition of qualitative research methods can counter many of the limitations of quantitative RCT data, allowing access to

'embedded processes' occurring in the setting by focusing upon the context of individuals' lives (Barber, 2014). Despite this, a recent review found only a third of recently completed RCTs of complex interventions included a qualitative element (Lewin et al., 2009). Most common, were those carried out before the trials; the aims of these studies included to develop or inform the study hypothesis, intervention or selection of outcome measures, or to understand the context of the setting. Other examples include the more classic anthropological study, which used a longitudinal ethnography- running alongside the trial- to explore professional research subjects' experiences of participating in clinical drugs trials (Abadie, 2010). As with many qualitative explorations of trial subjects, however, this application of qualitative methodology focuses on gathering data during the trial itself so was not intended to influence the trial design. An alternative approach to adapting trials to suit the proposed setting is the addition of a pre-design element. Webber (2014) used an orthodox longitudinal ethnography to develop a complex intervention for a planned trial in a social work setting, while another study used a 'targeted' ethnography to adapt a US HIV prevention to a Brazilian setting (Wainberg et al., 2007). However, both studies focussed solely on informing the interventions, rather than the trial design.

Another study had the long-term aim to increase patient adherence to medication and used a traditional ethnography to inform future research trials and direct future research avenues more generally (Gargeya and Holme, 2013), rather than a specific trial. Some researchers have utilised a pre-design component with the aim of informing the subsequent trial design but there have been questions raised about the methodology used. One research team used a rapid ethnography to

investigate breast-feeding practices in an area where they intended to implement an intervention to improve breastfeeding rates (Guerrero et al., 1999). Although they used the data to inform a planned trial, I would (in line with the majority opinion on ethnography's defining characteristics) suggest it cannot be classified as an ethnography due to the lack of participant observation which is generally considered to be the central feature of the methodology. A multiple explanatory case study design was used to explore the impact of the research setting within eight RCTs of complex interventions (Wells et al., 2012). Although the authors did not refer to this as a rapid or focused ethnography, the aims and methods used could be considered to be in keeping with this approach. Again this research focused on exploring the role of context within RCTs, rather than prior to their implementation. Interpretive phenomenological analysis with adolescent trial participants, their parents and physiotherapists delivering the intervention has been used alongside a RCT feasibility study (Toye et al., 2016). This led to specific recommendations for improved trial design in the pilot study but did not use an ethnographic methodology. Another study utilised a rapid ethnography to inform the design of a behaviour change sexually transmitted disease trial across five countries in a community setting (US National Insitute for Mental Health Collaborative HIV/Sexually Transmitted Disease Prevention Trial Group, 2007). Although the findings did lead to some alterations in the trial design, it mainly focussed on local adaption of the study intervention. As such, data collection was restricted to a very limited number of pre-defined features designed to inform the future intervention (i.e. behavioural outcomes, social groups to target, key stakeholders, potential recruitment sites), in contrast to the broader inductive stance required to inform the trial design from conception in this study.

Potential barriers may be encountered upon implementation of the trial that are not just limited to difficulties with the intervention itself: as such, if the methodology is too narrow or fixed it may not account for important contextual findings. We suggest there is potential in sequencing an ethnographic component prior to the RCT to inform the trial design (Kitchen et al., 2017). This approach has been used previously as a pre-design component to determine the feasibility of conducting a RCT (Turner-Halliday et al., 2014). A pre-design component to trials may be particularly appropriate because principle investigators are advised to make as few changes as possible during a trial in order to maintain the quality of the study (Kendall, 2003). A pre-design aspect allows the opportunity to identify and correct potential errors or pre-empt barriers in a first draft of the protocol, affording the chance to compromise between what is methodologically ideal and what is achievable within the clinical setting. Most importantly, a well-designed, methodologically sound RCT evaluating an intervention can be powerful in changing practice, which may in turn improve patient outcomes (Kendall, 2003). When this is considered in light of the Medical Research Council (MRC) guidance (Craig et al., 2008), that states context is a crucial consideration in trial design, what works in one setting may not be as effective or even be harmful elsewhere.

This pre-design qualitative study utilised a focused ethnographic methodology to inform a forthcoming RCT within a CAMHS context.

Principle research aim

To gain an understanding of the context into which Stage II of the research would be implemented; identifying the individual and organisational factors relevant to the design and feasibility of the planned depression trial.

Research objectives

- To document the staff culture, site procedures and facilities at the proposed site.
- To describe CAMHS patient care pathways for depression in this setting to inform decisions about the population, intervention, control group and outcomes.
- To understand staff attitudes towards research, the proposed trial and related training opportunities.

Methodology and method

Setting

This study focuses on a single large CAMHS team in the North East of England (one of the original proposed study sites for the Stage II of the research). Staff from this service are aligned to one of three providers, all centrally commissioned, based within the same site and composed of: Tier 2 (targeted services), specialist Tier 3 and Learning Disability (LD) services (Board of Directors, 2012, Affleck and Seed, 2015).[4] The focus of this study was on Tier 2 and Tier 3 services, which accounted for all patients except those with a clinically significant LD. The decision to exclude patients with LD was taken because the intervention had been designed for young people with a reading age closely matched to their actual age, which would exclude all young people from the LD service. The CAMHS service offers multi-disciplinary assessments, treatments and therapeutic interventions, which are provided onsite

[4] The full reference has not been included to avoid being in contravention of ethical agreements on anonymity.

and through outreach work for young people living within the local area, which has an approximate population of around 200,000 (Board of Directors, 2012).

The site is in County Durham, which is ranked in the top 30% of the most deprived authorities across England (Durham County Council, 2015).[5] Residents of County Durham experience particularly high levels of income, health and employment deprivation (Durham County Council, 2015). Mental health disorders, particularly those relating to mood and anxiety, appear to be a key driver of the high levels of health deprivation (Durham County Council, 2015). There has been an improvement noted in some areas of deprivation in the region, however child income deprivation has been increasing (Durham County Council, 2015). Child income deprivation refers to children living in families in receipt of income support, income-based job-seekers allowance, pension credit guarantee or child tax credit (Durham County Council, 2015); reflecting the increasing prevalence of inequalities for children in the area. These statistics give an impression of the difficulties typical families using the CAMHS facility face.

Methodology

An ethnography was conducted over a six-month period (October 2014 to March 2015). An ethnography can be defined as the study of social interactions, behaviours and beliefs that occur within a group from a shared setting (Barber, 2014, Reeves et al., 2008). However, the term ethnography has a dual use, as it refers both to the process of research and the written product of the study (Savage, 2000). In this case, the term ethnography has been used to refer to the methodology for conducting the

[5] The concept of deprivation reflects various socioeconomic inequalities between and within areas, across seven distinct domains of income, employment, health/disability, education/training, barriers to housing and services, living environment and crime (Durham County Council, 2015).

research, rather than the resulting narrative composition. Ethnography was the most suitable methodology for addressing the research aim in this setting as it ensured an appropriate and rigorous approach to data collection, providing rich, holistic insights that could not have been obtained from alternative approaches such as surveys or focus groups. The approach allowed staff knowledge to be meaningfully contextualised, and space to consider personal, interpersonal, managerial and societal influences on behaviour. Savage (2000) notes that, for these reasons, an ethnographic approach can be particularly useful in pre-design stages of research, to provide the depth and breadth of data required. For instance, Gargeya and Holme (2013) describe the benefits of using ethnography at the early stages of a pharmaceutical clinical trial, stating that the approach takes the data "from insight to impact within the tightly-defined scope of clinical trials" (p166). They note the seeming incompatibility of these disparate methodologies; a clinical trial representing a controlled, artificial environment and an ethnography seeking to observe the real-life uninhibited realities of the setting. Although these methodologies seem contradictory, the importance of context is the unifying feature. In an ethnography, all learning is cited in the unique context of the setting in which it occurred whilst, in a trial, context is vital in order to control the potentially confounding impacts from the environment.

There has been confusion and disagreement amongst academics as to the essential features of an ethnography. The defining element, upon which most agree, is that an ethnography involves some aspect of participant observation, which crucially allows examination of issues in the context in which they occur (Savage, 2000). Another issue of contention arises as new models and applications for

ethnography are undertaken, which challenge some of the established features of traditional ethnographies. One such feature is the amount of time spent by the ethnographer in the field. Historically, ethnographies were defined by their time-intensive nature, where researchers would spend many years immersing themselves in novel cultures. In the 1980s, models for more rapid assessments of settings were found to be useful to inform interventions (US National Insitute for Mental Health Collaborative HIV/Sexually Transmitted Disease Prevention Trial Group, 2007) which are often referred to as rapid, focused or micro-ethnographic methodologies (Cruz and Higginbottom, 2013). Since then, guidance on how focused ethnographies can be used in healthcare settings to specifically address distinct issues or shared cultural experiences has been produced (Cruz and Higginbottom, 2013). The ethnography described in this thesis was 'focused', in that I entered the field with established research questions in relation to the participant observation aspect of the data collection, which served to shorten the length of fieldwork required. The active intervention arm of the proposed trial had already been identified as Behavioural Activation (BA). The pre-defined research questions were:

1. Is there a need for BA therapy in this service?
2. What would be the barriers to implementation of a RCT of this intervention?
3. What are the normal care pathways for patients with depression in this service?
4. How might a BA RCT fit into these existing pathways?

The length of the participant observation was also 'focused' by the need to inform the subsequent stage of research within the timeframe of a PhD. For this reason, the

study was undertaken over a period of six months. The focused approach has been criticised for not allowing sufficient time for the researcher to become fully integrated into the setting, raising questions relating to the validity of the observations. Focussed ethnographers have responded to this by placing greater emphasis upon the findings from participant interviews; as the research questions are pre-defined, they can more easily be explored using this method (Cruz and Higginbottom, 2013). Therefore, in contrast to a traditional ethnography, the descriptive core of this study is more reliant on staff interviews. Participant observation and other methods applied have been used to contextualise the resulting analysis and aid interpretation.

Data collection methods

Savage (2000) has argued for the greater use of ethnography within health care research as it enables the combination of a range of both qualitative and quantitative methods, thus benefiting from both individually and in complement. In this case, data was collected for this ethnography using participant observation, document analysis and interviews, each of which will be discussed in further detail below. The use of these seemingly disparate methods is guided and unified by the overarching ethnographic methodology. And, as in the rest of the thesis, I took a reflexive approach to the conduct of this study. Reflexivity enables attention to be focused upon the process of knowledge construction, especially to the effect of the researcher (Mason, 2002). This is crucial in an ethnographic approach, owing to the relationship between the researcher and the participants (Reeves et al., 2008). Three data collection methods were selected to ensure that a multi-facetted picture of the setting was obtained in the short time period available for data collection.

Participant observation

Participant observation affords the opportunity to view behaviour in a naturalistic setting and therefore to understand beliefs and actions in context (Mason, 2002, Barber, 2014). Participant observation was undertaken throughout the ethnographic study period on a purposive basis, providing evidence of staff behaviours, culture and real-life decision-making and compromises. Data collection was purposive in the sense that it was not systematic nor was information sought out in a pre-determined fashion. Rather, informal discussions with clinicians, who I understood were likely to shed informed light on particular subjects, led to an in-depth understanding of staff backgrounds and clinical activities. Participant observation also allowed information to be generated that related to the administrative procedures surrounding patient depression pathways through the service.

One key advantage of participant observation is the opportunity to counter the socially desirable responses that may be met using other methods, and to allow observation of behaviours that staff have become unaware of (i.e., entrenched or tacit behaviours) or those that they are unwilling to articulate. This enables the identification of inconsistencies in the way staff present themselves (for example, when compared with the findings from formal interviews) with how they act in everyday practice, illuminating any discrepancies between intent and outcome (Barber, 2014). For this reason, participant observation and interviews were utilised alongside each other to gain a fuller picture of everyday realities for staff in the service. Documentary analysis was completed alongside participant observation to allow a comparison between the information available and how protocols are

interpreted by staff as this is likely to shed light on how new procedures may be adopted by the service (Barber, 2014).

Participant observation differs from many qualitative methods in that it involves minimal interference from the researcher (Barber, 2014). Despite this, attention needs to be given to the integration of the researcher into the research setting. In this study, integration within the CAMHS team was achieved by conforming to the expectations of the setting in terms of dress code, working hours, taking on a clinical caseload appropriate to the honorary role, being added to the team mailing lists, using desks in the CAMHS offices, as well as attending a variety of meetings and supervision sessions alongside existing staff. Prior to data collection, I undertook all usual National Health Service (NHS) Trust induction procedures, such as reading the staff handbook and attending IT training, in addition to familiarising myself with the NICE guidance for depression in Children and Young People (National Institute for Health and Clinical Excellence, 2005). All other guidance or training was provided once the study period had commenced. Extensive descriptive notes were made in a field diary during and following each visit, including any reflexive summaries. During meetings, I often volunteered to write the meeting minutes in order to normalise my note taking with a view to reducing the impact of an observer on routine behaviour. In other circumstances, I made notes immediately following informal conversations or observations rather than during such encounters, so as to not make staff feel uncomfortable. A benefit of using an 'informal' approach to data collection enables the ethnographer to probe emerging issues or ask questions about unusual events in a naturalistic manner often leading to candid responses (Reeves et al., 2008).

The information generated using this data collection method was then used to inform the development of an interview schedule for the formal interviews. As areas of interest were observed, they were investigated- or tested- further by way of informal discussions or explored via the formal interviews. All clinical and administrative staff were invited to participate in the observational element and there were no exclusion criteria.

Formal interviews

One-to-one interviews are the most common qualitative data collection method (Barber, 2014), and also form part of an ethnographer's suite of data generation tools. Interviews can vary from being completely unstructured, allowing participants to talk about any topic they wish, to those that are tightly focussed upon the topic of the researcher's interest (Clough and Nutbrown, 2012). In this study, semi-structured individual interviews were selected in order to explore the pre-defined research areas but with the complement of open-ended questions that offer interviewees the freedom to highlight issues of importance in their own decision-making processes (Mason, 2002). The interviews were designed to illustrate staff's understanding of the information and treatment guidance issued in relation to depression, barriers and facilitators to implementation of this guidance and the proposed study. In addition, the aim was to collect or confirm information on staff opinions and observations, particularly on sensitive topics that they may be reluctant to discuss in front of other members of their team. The resultant staff narratives provide a rich, thick description of their experiences and opinions (Ponterotto, 2006). Alternative methods such as focus groups may have restricted staff's willingness to discuss sensitive topics in front of their colleagues and caused practical

difficulties with finding a suitable time for numerous staff to congregate in the context of a busy service.

Key stakeholders for the interviews were identified during the participant observation stage and the identified staff were then invited to attend formal interviews. The interviews were formal in the sense that they were booked in advance, followed an interview guide, took place in a private office and were audio recorded. It is common for ethnographic questions to emerge from the field. An interview guide covering the core topic areas had been pre-prepared during the period of participant observation and was amended to explore emerging concepts that arose in the field or previous interviews (see Table 3). Interviews were audiotaped and transcribed verbatim using an encrypted Trust-approved recording device. Interview participants were offered the opportunity to read through their interview transcripts following the interview and were invited to indicate extracts that they preferred were not used in verbatim quotes; this approach has been used in previous research (O'Cathain et al., 2014), but was used in this case at the request of the Team Manager.

Table 3: Interview Topic Guide

	Staff interview questions
1.	What treatments do patients with depression, aged 12 to 17, usually receive in your service?
2.	How do you think a new talking therapy such as Behavioural Activation (BA) will fit into the existing care provided by the team?
3.	How do you personally feel about the prospect of a trial of this new treatment in your service?
4.	How do you think other members of staff feel?
5.	Are there any reasons that you think a trial of BA might be difficult in your service?
6.	Are there any benefits to offering a new treatment such as BA?
7.	Are there any negatives?

8. What could we do to ensure the smooth implementation of the trial?
9. Do you have any other thoughts that you would like to share?

Document analysis

Documents can be a useful source of information, particularly relating to policy (Barber, 2014). Rather than just being an 'inert' product, documents are often linked to individual's everyday practice and routine (Barber, 2014). Documentary analysis can therefore shed light onto individual actions and processes in the context that they occur. Documentary data were generated through analysis of relevant paper and electronic documents collected during the study period on an opportunistic basis. Data was not collected systematically because this would not represent the way in which information was disseminated to staff. Instead, by being added to staff mailing lists, reading staff notice boards and attending team meetings I encountered information in the same way staff within the team would in their day-to-day practice. The aim of this approach was to embed myself, as far as was possible, into the natural staff setting and experience the information flow as a staff member. The purpose was to obtain basic facts about the service, its protocols and enable an understanding of the information flow throughout the team.

Ethical considerations

Ethical approval for this project was obtained from the Durham University School of Medicine, Pharmacy and Health Ethics Sub-Committee (ref: ESC2/2014/06; see Appendix 2) and it was registered with the local Trust Clinical Assurance and Registration Steering Group Committee (ref: 4188CYPS14). The study was discussed with the National Research Ethics Service as no patients were involved in this study, NHS ethical approval was not deemed to be required.

There were a number of ethical considerations when designing this study. Participant observation itself raises many issues, particularly surrounding participant consent (Mason, 2002). For this reason, efforts were made to ensure the consent procedure allowed staff to decline participation and did not cause undue distress. Prior to the start of the study, a PowerPoint presentation was given to the team about the ethnography, followed by a question and answer session for staff. All members of the CAMHS team (n=26) were then invited to participate; these staff members received a paper information sheet (see Appendix 3) and were able to 'opt-out' of the study by completing a form and returning it to a sealed box in a staff communal area. This allowed staff to opt-out without their Team Manager's or colleagues' knowledge, lowering the chances they would be coerced into participating. There was no paper consent form at this stage as, on balance, this seemed to be an unnecessary staff burden. Therefore, in the absence of receiving a completed opt-out form, staff were assumed to agree to participation. Participants were regularly reminded of my role as a researcher and offered the opportunity to be removed from the study at any time. If staff opted out, no further data would be recorded relating to them from that point onwards but they were made aware in the information sheet that any data collected prior to this point would be retained. The reason for this is that the field notes were recorded anonymously, referring only to staff grade (not individuals) so it would not be possible to review the field diary and remove references to that staff member. Furthermore, even if staff opted-out, they would still be present whilst observations of other members of the team were being completed. Although opt-out participants would not be commented upon in the field notes, they also could not fully be excluded from the research process. During the

study observation period, only one opt-out form was received, this form was received on the final day of the observation. This staff member was not present for any observations on the final day so no data had to be overlooked.

Despite the favourable recruitment rates, I had cause to reflect upon the success of the first contact made with staff as part of the study. I approached staff with a paper information sheet and a formal consent protocol that was both unfriendly and immediately alienated myself from the team. I highlighted myself as the researcher and thus staff as the subjects of my research; I was subsequently regarded with suspicion and apprehension at the start of the observation period, which took many weeks to overcome. The damaging impact of this can be demonstrated by several incidents during the first weeks of the observation; when I approached groups of staff engaged in conversation, they would awkwardly trail off their discussions upon my arrival. On reflection, the consent process could have been better aligned to the aims of the study by being more informal or the formal consent process occurring in advance of the study with reminders once the research started. This has to be weighed against the necessity of staff being fully informed about the ethnographer's role and the purposes of the research.

Once staff had been identified as a key member of the team, they were invited to the formal interviews either verbally or by email. At the start of each interview, staff received a paper information sheet and were asked to complete and sign a paper consent form (see Appendix 4). This consent procedure also felt very formal but was appropriate to the sensitive nature of some of the topics that could be covered during the interviews.

Other commentators propose an 'embedded' approach to ethnography to enable the researcher to see the 'world view' of the organisation (Lewis and Russell, 2011). This raises concerns about ensuring separation between the role of researcher and that of a CAMHS team member and how these dual roles would be managed during the study. This was addressed by ensuring that staff were clear about the purpose of me being onsite by making repeated reminders during the observation, as well as via the information sheets and presentation made to the team. Power differentials often exist between researchers and their participants (Barber, 2014). This is particularly common in observational studies but was less sensitive in this situation due to my lower ranking honorary position in the team as an Assistant Psychologist, where I was generally equal to or below all members of observed staff within the team hierarchy. However, it remained a risk that staff may have had anxieties sharing knowledge with me, particularly if this related to information that may portray their team negatively or highlight errors in their own practice. This risk was outweighed by the opportunity for the research to identify and report poor practice. In addition, staff members were offered the opportunity to read back through their interview transcripts prior to analysis. This reflected the sensitive nature of some of the topics covered and was designed to increase staff participation in the study (at the suggestion of the Team Manager). Perceived pressure from the service to report favourable findings may also have been an issue; this was addressed using reflexivity in the field diary and transparency in the reporting of the study.

It was also a possibility that patients may have been indirectly observed (i.e., if a service user representative attended a staff meeting) so it was agreed to remove

any references to non-staff members in field notes and transcripts. Similarly, staff details were removed from interview quotes to preserve anonymity. These were in addition to the usual considerations around information governance and preservation of confidentiality. Data was stored in a de-identified manner, according to Trust and University guidelines and digital recordings were securely destroyed following transcription. Paper data will continue to be stored for three years from the end of the study.

Researcher dispositions

Initially I felt very uneasy about observing others. Like previous ethnographers in similar settings (Cudmore and Sondermeyer, 2007), I found that as my research progressed, my role within the team changed; however, the direction of that change was in the opposing direction. While Cudmore and Sondermeyer (2007) reported becoming more objective ethnographers, I felt myself sympathising increasingly with the staff, whereas initially I had viewed them more objectively.

As a white female with English as my first language, I matched the profile of the vast majority of the team. I also shared common attributes such as being non-disabled, heterosexual, being born in the North East of England and educated to degree level, with a background in health/psychology. I differed from many members of the team in that my accent was considered “posh”, and I was identified as “not a local” as I did not live in the same geographical county. I was also younger than many staff and did not have an employment contract with the Trust. Some of these judgements were transient; early judgements were later challenged during the course of the study. For example, after I referred to my umbrella as a “brolly” a nurse stated she was satisfied I was from the North East, despite my “funny accent”.

Lewis & Russell (2011) reported similar preconceptions and expectations about researchers whilst undertaking an ethnography in the North-East of England. My positionality was particularly important in light of the way meetings were often segmented by discipline; for example, the 'psychologists' often met separately to the Clinical Nurse Specialists. I naturally was accepted into the psychology aspect of the team due to my undergraduate psychology training.

Dispositions are not only based in such "demographic" considerations, but also personal or scientifically contingent world views. Although there is no consensus among ethnographers about the epistemology, or theory of knowledge, that underpins an ethnographic account it was still an important element to consider (Savage, 2000, Mason, 2002). Similarly, ontology or the beliefs about the basis of the 'social world' also required thought (Mason, 2002, Barber, 2014). Historically, positivism has been a dominant viewpoint, which understands the natural world as something that can be controlled, resulting in a measurable and singular truth (Barber, 2014). A positivist stance is taken in Stage II of the research, where a trial methodology is utilised; in contrast, this focused ethnographic study (Stage I) approached meaning and knowledge from a constructionist perspective. This necessary shift in perspective reveals some of the difficulties in marrying and integrated mixed methods research into a coherent body of work. Constructivism argues that there is no ultimate objective reality, instead the social world can only be perceived by the individual (Barber, 2014). In the case of this research, this view holds that the researcher and staff are making sense of their reality by attributing and constructing meaning in relation to the setting. Thus, there is no intention to try to distil this meaning by attempting to quantify observations.

Data collection

In all, seventeen documents were collected (consisting of meeting minutes, emails and a PowerPoint presentation), 158 hours of observation were conducted and six staff interviews (lasting between 16-25 minutes) were undertaken. Staff observed included Team Managers, Consultant Clinical Psychologists/Psychiatrists, Clinical Psychologists, Clinical Nurse Specialists, a Specialist Advisory Teacher, an Administrative Coordinator, a Community Clinician, a Child Psychotherapist, CAMHS Clinicians, an Associate Practitioner, an Associate Specialist, a Research Assistant and an Assistant Psychologist. A manager headed each 'Tier' of the team; both managers (Tier 2 and Tier 3) had a clinical background and one also had prior research experience. Staff came from a vast array of professional and non-professional backgrounds; predominantly nursing, psychology and psychiatry but also social work, commissioning, research, addiction services and unskilled care roles. All staff asked, agreed to be interviewed (identified key stakeholders who were invited to interview can be seen in Table 4). Some staff were very comfortable in the formal interview environment and answered questions directly and comprehensively. Others were more guarded and one particular manager's responses sounded automated as if they were reading from a script. No amendments were requested to be made to the interview transcripts by the participating staff. The meetings observed ranged from informal, spontaneous meetings with only two staff present, to official meetings headed by a manager where agendas were circulated in advance and official minutes recorded.

Table 4: Pseudonyms and characteristics of the formal interview participants [6]

Pseudonym	Tier	Affiliation
Joan	2	Specialised
Claire	2	Managerial
Leanne	3	Junior
Jackie	3	Psychology/Managerial
Judy	3	Managerial
Sarah	3	Psychology

Data analysis

Mason (2002) refers to ability of qualitative research to intimately connect context with explanation. Staff accounts therefore, have to be situated in the context in which they were stated. An inductive approach was taken to data analysis to enable meanings to emerge from the data through in-depth examination of all the data sets. This analysis occurred at the end of the data collection period drawing on experiential knowledge from the field, with the exception of the interview transcripts, which were reviewed following each interview in order to alter the interview topic guide to explore emerging issues.

As the ethnographer, I transcribed each interview transcript and typed up field notes into an electronic format in order to re-familiarise myself with the data. Data were coded for emergent themes, which were verified by a second coder (Patrick Welsh) independently (Braun and Clarke, 2013). I read the interview transcripts and other data sources several times to familiarise myself with the data prior to applying thematic codes according to the principles of Braun and Clarke (2013). The second coder read through the data sources independently and a meeting was then held between both researchers. As the ethnographer, I led this

[6] Notes: 'Junior' refers to unqualified staff; 'Specialised' to nurses or Primary Mental Health Workers (PMHWs); 'Psychology' to any qualified professionals aligned to psychology and 'Managerial' any staff members with significant managerial responsibilities.

meeting where I discussed the identified themes with the second coder and provided the contextualisation necessary to assist the second coder's interpretations and then a consensus was reached. A second coder was employed in order to help manage objectivity, an approach that has been used previously (Wells et al., 2012). This sits somewhat at odds with the traditional concept of a longitudinal ethnography, where the knowledge of and basis for interpretation by the ethnographer has been honed over many months or years of participant observation. In such circumstances, a second coder would not have the capacity to assist in data analysis. In contrast, this focused ethnography was more reliant upon interview transcripts. The benefit of a focused approach lies in the opportunity to expedite the data collection, with any "shortfall" in time spent in the field compensated for by enabling multiple coders to participate in the analysis, offering the opportunity for reflection upon the findings.

Methodological triangulation was used to provide more comprehensive insights into each emergent theme (Savage, 2000). Data triangulation generally refers to the collection of data on the same topic utilising differing methods of data collection (Reeves et al., 2008). The term itself can be misleading, implying a precise focus (illustrated by the converging data collection methods) and thus, a positivist epistemological basis for the study (Mason, 2002, Barber, 2014). More recent modern commentators have distanced themselves from these "quantitative" connotations. They instead use the term 'crystallization' (Barber, 2014), which describes the use of different datasets to look at the same phenomena through a different lens. Instead, in this study the term triangulation is more loosely used to refer to establishing corroboration or contradiction either between differing

methods but also between different participants' accounts of phenomena. Crucially, this acknowledges and enables exploration of the sources of apparently alternative explanations.

Another important consideration was my role in the data collection and analysis, as it is acknowledged that I was responsible for selecting which data to collect and which data to present in this thesis (Mason, 2002). As previously discussed, reflexivity is the consideration of the impact the researcher has had on the data collated and on the research process (Barber, 2014, Mason, 2002): this impact was reflexively under consideration throughout the study, in order to delineate the effects of a sole researcher on data collection methods and methodology.

Results

Presentation of the results

The findings are presented in the form of a thick description of research encounters in the aforementioned CAMHS team; this format lends itself to illustrating the complexities of the setting in a clear format. Lengthy quotes alongside interpretations are an accepted way to present such ethnographic data (Ponterotto, 2006). Some data have been presented visually, which has been recommended as a way to illustrate themes or concepts (Mason, 2002), rather than relying upon a conventional textural description. This approach was thought to be particularly useful for readers who are not familiar with reading qualitative or mixed methods research. It is important to note, then, that the presentation and content of this chapter will differ markedly from what one might expect from a thesis centred on an

RCT. Additionally, as previously mentioned, the main body of these qualitative results leans more heavily on formal staff interviews, which differs from the usual presentation of ethnographies that emphasise the findings from participant observation. The tone and manner of presentation of the following narrative reflects these caveats.

The site

The outside of the CAMHS building does not immediately reveal its purpose, except for the tell-tale blue and white NHS sign subtly displaying the building's name. The car park is full to capacity, as are all access roads, with staff and carers' cars. Once inside, the impression is friendly and child-focussed, with brightly coloured chairs, walls and toys on display in the waiting area. The ground floor of the building is designed to be patient-facing, whereas the staff-only second floor is clinician-facing. Downstairs there are a large number of treatment rooms that are well kept, colourful and varied. Upstairs there are two large open-plan offices lined with computer desks, and private offices lead off from this main space. Upstairs is relatively barren compared to the colourful, chaotic environment downstairs, with little personalisation of walls or desks evident. Centrally, there is a communal space, which is reserved for lunch and staff meetings, as well as a small kitchen. The first time I enter the upstairs staff area, I am hit by the noise of staff talking and phones ringing. My immediate panic was where to sit, as most desks appeared to be occupied and no one seemed aware of my presence. After finding an unoccupied desk, I sat down and tried to be friendly. Staff situated at desks around my computer were busy but responded by being friendly in return. This became 'my desk' (according to my new colleagues), despite the strict NHS policy that every desk is a

'hot-desk' available for anyone's use and the fact that, on many occasions, I arrived to find my desk otherwise occupied by one of the many staff who use the site. The allocation of my own space grounded me within the setting and provided reassurance of my acceptance within the team.

The research commenced at a time of considerable change within the service format of CAMHS. As such, the enduring impression of the setting was of a chaotic service experiencing an intensive period of change. At the start of the placement, I found it difficult to concentrate due to the bustling environment and the chatty nature of the staff. Several weeks later (subsequent to the start of the ethnography), a new initiative to increase working hours was introduced, extending consulting hours to 12 hours a day Monday to Thursday as well as additional coverage on a Saturday. There were no additional staff members allocated to compensate for these changes, which resulted in staff being spread more thinly, greatly impacting upon the atmosphere and morale of the team. This was one of many 'initiatives' staff felt had been laden upon them in this time of austerity. I certainly found I had to adapt to changes in the service's circumstances, politics and policies over the relatively short period of observation.

During my time in the service I shadowed various staff members in their usual roles, selecting the staff member to shadow was largely decided on a pragmatic basis of which staff had patients with low mood on that day. I rotated days and times during my placement to ensure I gained a rounded view of the service. I was invited to meetings at a team, professional (i.e., psychology) and individual (i.e., case discussions) level.

Themes from the data

After analysing the resulting ethnographic data, four themes emerged; non-clinically orientated variance in practice, diagnosis, capacity and staff economy. As can be seen in Figure 5 there is significant overlap between the themes, with staff economy being central to the other themes but also a distinct theme in itself. The thematic content has been summarised in Table 5 and the results are presented in further detail below, in terms of the factors that impacted upon elements of the planned trial.

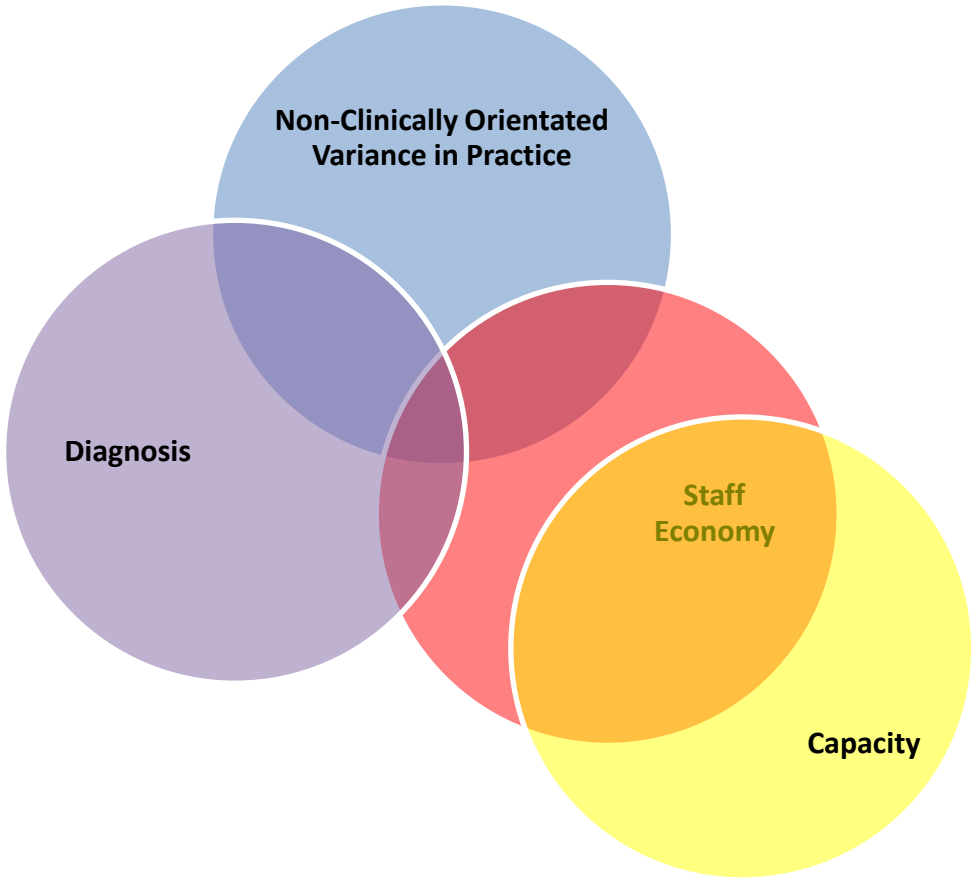


Figure 5: Diagrammatic representation of the identified themes

Table 5: Four emerging themes

Theme	Description
Non-Clinically Orientated Variation in Practice	This theme involves changes to practice described by staff, including the rationale for treatment decisions that are often based upon resource availability rather than clinical need.
Diagnosis	This theme consists of staff beliefs and behaviours relating to the treatment and diagnosis of depression.
Capacity	This theme consists of the time to engage with research or to attend training and space to psychologically consider or incorporate learning into practice.
Staff Economy	This theme is characterised by staff changes and shortages.

Non-clinically orientated variance in practice

It was important to explore how staff responded to the current guidance surrounding the treatment of young people with depression. Interviews and observation suggested staff have a good working knowledge of the NICE guidance relating to the treatment of depression in children and young people (National Institute for Health and Clinical Excellence, 2005). Furthermore, documentary analysis provided evidence that information relating to this guidance was disseminated to the team during the study period. Despite this familiarity, barriers to implementation of the guidance were identified that subsequently led to disparities in patient management. In situations where NICE treatment was not offered, staff were generally aware that they were deviating from the recommendations and expressed a desire to maintain "evidence-based practice". The treatment patients received depended upon a number of factors such as the previous training staff had received, the Tier of care to which the patient was allocated for treatment and staff's personal preferences. There were two sub-themes within this strand; the impact of

staff's differing backgrounds and the impact of a stretched service, each of which will be discussed in further detail.

Impact of staff backgrounds

In relation to how staff would currently treat low mood or depression in Tier 2 of the service, Claire (Tier 2 [T2] Managerial) explained that due to the diversity of staff within the team, "at the moment, it's a bit of a hit-and-miss scenario". As Joan (T2 Specialised) explained, this variability between different staff members could be explained by the different roles that staff had undertaken prior to joining the CAMHS team and the impact their differing backgrounds had on their approach to treating patients: "I think cos we tend to go and do different things. We're all different backgrounds, PMHWs [Primary Mental Health Workers] and we all have different ways of treating people".

Linked to this were suggestions that some members of staff struggled to adapt to the ever-changing job roles that were a common occurrence as the service attempted to cope with a battery of changes, and which staff blamed on austerity measures. The impact of these changes was tangible within the team and was raised an inordinate number of times in casual conversations, formal meetings and correspondence.

Staff had assorted training backgrounds, and a variety of training opportunities were available to them during the period of the observation. The desire to implement evidence-based practice was highlighted by the team several times both when staff were observed and when they were interviewed; some staff were able to achieve this by attending accredited training programmes through the Children and Young People's Improving Access to Psychological Therapies (CYP IAPT)

Service Transformation Programme, whereas others learnt the required skills second-hand from colleagues. Staff expressed a preference for members of the team to have received formal training and highlighted this as a way to improve current practice in treating young people with depression. Staff described these two differing approaches to learning psychotherapy skills, using the Cognitive Behavioural Therapy (CBT) model as an example:

> "We've had some CAMHS staff that has been off to do IAPT so they have been trained in CBT… there's a lot of the staff that's got that awareness level of CBT so although they can't use CBT in, in such form they can use approaches of CBT" [Claire, T2 Managerial]

> "[To improve current practice: young people need] access across the board to someone who's CBT-trained and if they're not getting that then I would kind of be asking what are they getting from a clinician who isn't CBT-trained? But whether they've kind of obviously picked up the principles and haven't had formal training but they've done kind of workshops and that kind of thing and just from experience because they've been in CAMHS for 20/30 years kind of thing. That they're able to kind of, I suppose they know what they are doing and what's worked in the past for their clients with depression" [Leanne, T3 Junior]

In response to this, staff noted incongruities between the treatments being offered to patients due to the different training that staff may have undertaken. Some staff raised concerns about the implications of learning therapeutic skills informally. One staff member was concerned that young people were being treated for depression in Tier 2 but were not receiving evidence-based practice:

> "Depression is, if you don't deal with it early on, it can reoccur and it, it can be really debilitating for people so we need to tackle it and treat it at this early stage [in Tier 2]. I don't have a concern with it being treated in Tier 2, I do have a concern about it being treated in Tier 2 by staff who aren't trained in the treatments for it" [Jackie, T3 Psychology/Managerial]

An informal approach to staff supervision was also observed; during staff discussions informal advice and support were offered about how best to treat patients.

Impact of a stretched service

Compounding the variances in training across the CAMHS team, there are a number of tensions within the service that made it difficult to deliver treatment according to the recommended NICE guidance. Sarah (T3 Psychology) reported that young people allocated to Tier 3 currently had to be assigned to a clinician for treatment "based on space rather than need". Several narratives referred to this patient management approach and detailed how young people in the service were assigned to care:

> "[I]t depends on what information we get and it depends on what staff we've got. If it's a young person that they, you know that's presenting with some depression and we haven't got a CBT appointment then we'll put them into another appointment" [Judy, T3 Managerial]

> "Well I suppose [ideally] it would depend on the clinician individual approach…adhering to the guidelines really and I suppose the young people being assigned to the most appropriate people for their difficulties. I know that doesn't always happen because of the sheer volume of referrals and lack of capacity that we've got" [Leanne, T3 Junior]

> "[T]he really bad point is really that if we need specific CBT …we then have to put it into Tier 3 for them to have that because actually we haven't got enough CBT practitioners in Tier 2 but that doesn't, that doesn't mean that the young person should be in Tier 3. It's just, that's the only way they access CBT" [Claire, T2 Managerial]

Staff explained that these treatment decisions were based upon the availability of resources rather than the patient's clinical need. This can be linked to another identified theme from the data, which will be explored in further detail below, which is that of staff economy. Notably, there were not enough staff within the team to provide treatment according to NICE guidance due to staff capacity being reduced, and also there being too few staff who were adequately trained in NICE recommended therapies. These difficulties were observed *in situ*, as illustrated in a field note entry:

> "Recently the team have been allocating referrals to any clinician (unless a specific treatment such as CBT has been suggested). This means that they are not [made] based on their severity (i.e. more severe cases are not seen by more experienced clinicians currently)" [1.45pm, 3rd Dec 2014]

Management noted "it's better that [patients are] seen than wait" highlighting the difficult decisions and compromises that have to be made in a stretched service. Furthermore, staff and patient preferences were often unable to be effected due to the burden of large caseloads, with staff reporting an inability to see patients in a weekly or bi-weekly format which they felt was required for successful treatment. Leanne (T3 Junior) complained that "it's too long between sessions, [we] need to keep the momentum going and the progress". I sensed that staff were attempting to cope with these difficulties by implementing what they see as short-term measures or 'fixes' in order to process the vast number of referrals the service has been receiving. Staff often shared their hopes that the situation would improve so that these difficult compromises no longer needed to be made.

Diagnosis

Beliefs surrounding diagnoses were divergent and rooted in staff's professional training backgrounds; paralleling the impact of previous staff experiences on patient care in the non-clinically orientated variance in practice theme. This concept can be illustrated in a vignette involving Jackie (T3 Psychology/Managerial), who has undertaken postgraduate training in psychology. She recounted, in utter disbelief, an encounter with a Tier 3 nurse who had recently completed a CYP IAPT training course to become a CBT therapist. The nurse had explained to Jackie that it was one of her core beliefs as a nurse that you do not diagnose. Despite moving from an assessment-based to a treatment-based role, the nurse was reluctant to treat young

people who had received a 'clinical diagnosis'. Jackie had probed whether it was possible to treat any patient without identifying the condition being treated, and then questioned the nurse with sarcasm, "identifying something as depression goes against your core belief of your profession?" Jackie had concluded by advising the nurse to re-evaluate their standpoint in light of their recent re-training as a psychotherapist.

Despite the often disparate views that are grounded in staff's professional affiliations, staff agreed on whose role it was to diagnose depression. Staff in Tier 2 clearly articulated that diagnosis did not fall under their remit:

> "No, in Tier 2 we wouldn't diagnose depression. We would obviously pick up the signs and symptoms from the young person's presentation and the ROMs [Routine Outcome Measures]. Using tools, but if they wanted a clinical diagnosis of depression then it would have to go to a Consultant in Specialist CAMHS" [Claire, T2 Managerial]

It was also clear that depression was rarely seen in isolation and was often accompanied by a myriad of comorbidities. Audit data collected whilst on site confirmed that 60% of patients experiencing low mood or depression had at least one comorbidity. Interestingly, staff noted diagnoses of depression were rarely made in practice: this was observed, as well as reported in interviews. The ramifications of this were evident when, during a team meeting, a 'depression pathway' that had been recently piloted within the service was discussed. This treatment pathway required patients to have received a formal clinical diagnosis of depression. The substantial clinical burden of patients with depression was illustrated in a PowerPoint presentation given to the team where depression was highlighted as one of the most prevalent conditions that the service treats. Yet, due to the fact that the vast majority of these patients had not received an official diagnosis, the depression

pathway could not be implemented due to a lack of eligible young people. There was discussion during the team meeting about how to solve this issue but the action decided upon was to feed it back to the commissioner of the pathway as the team did not have the resources to address the problem. Furthermore, staff lacked confidence in decision-making surrounding depression, often relying upon the expertise of specific professionals within the multidisciplinary team:

> "Often people send [patients] to a medic [Psychiatrist] because they want the medic to make the decision because they don't feel confident doing it themselves' [Sarah, T3 Psychology]

In this context, some staff tended to separate the symptoms of depression from a clinical diagnosis of depression itself. They placed importance on the concept of a diagnosis, indicating this may alter the way they worked with patients who had received a clinical diagnosis:

> "When you talk about depression though, do you mean clinical depression, that's got a diagnosis?" [Joan, T2 Specialised]

> "Not if it's clinical depression, no we wouldn't [treat it], no we would treat low mood but young people will often tell you that they're depressed without having the diagnosis criteria for depression…" [Joan]

There was agreement on where depression should be treated within the service structure: low mood or depression without significant self-harm in Tier 2 and depression with self-harm or severe depression without self-harm within Tier 3. Staff identified what they termed vague, early onset or early-stage depression that would sit within Tier 2 but some staff felt Tier 2 should not be allocated patients who had received a diagnosis of depression at all.

> "I think if we could, I think depression probably shouldn't sit in Tier 2. I think it should sit in Tier 3. But I think we should have more people in Tier 3 so that if Tier 2 gets a whiff of depression they're not keeping it, they can pass it straight in" [Sarah, T3 Psychology]

Treating young people who had received a diagnosis of depression could be stress-inducing for staff. Lower-grade staff in particular, described a lack of confidence in dealing with young people with a diagnosis of depression:

> "I have to say that I tend not to keep people who have [a diagnosis], particularly if they think they're depressed. Low mood I might keep them for a little while but I'd tend to pass them on. I'm quite risk adverse really. And not being mental-health trained…" [Joan, T2 Specialised]

> I think that by highlighting to people that what they are dealing with is depression then it might raise their anxieties a little bit" [Jackie, T3 Psychology/Managerial]

In contrast some staff felt confident dealing with depression in their roles within Tier 2. Joan (T2 Specialised) commented:

> "There are some people [members of the Tier 2 team] who'd hold onto them because that's their background"

Again, this highlights the influence of staff backgrounds as illustrated in the non-clinically orientated variance in practice theme. Concerns surrounding staff confidence were expressed at senior levels of the Trust. For example, an email from the Trust Chief Executive noted a lack of self-confidence when it comes to decisions about what information to communicate to friends and family of patients who are receiving treatment in the Trust.

Staff suggested a barrier to patients with depression being treated in Tier 3 is a lack of staff capacity. This parallels the staff economy theme that appears to be an explanatory factor in many of the observed individual and managerial decisions made in the service.

Capacity

There were two uniting aspects to the capacity theme; time and psychological capacity. As I was planning for a pragmatic trial, where the intention was to train

existing staff from the service to deliver the intervention, it was important to explore staff perceptions towards the different types of training that were currently available to the team in order to evaluate how the BA training may fit into this context. 'Headspace' was the term used by participants to describe the mental capacity to consider training, as well as the opportunity to mentally incorporate or absorb this learning in order to be able to implement it into their everyday practice. Staff made a distinction between these two converging aspects of "time and space" or "headspace and capacity". Staff felt their needs relating to the physical aspects of time were being better met than those related to the psychological side, which were often overlooked.

Psychological capacity

Psychological capacity is the time or headspace for staff to mentally consider the training opportunity or incorporate the learning from training courses into practice. When Judy (T3 Managerial) was asked what would influence staff to utilise training opportunities, she responded: "headspace and capacity I would say are probably one of the main things". One member of staff used the term headspace to describe her thoughts whilst considering taking part in training:

> "I do think they would really want to do it and find it helpful but it's gonna be the way that they are approached really because, headspace. If you catch someone on a difficult day and they're back to back with clients they might not have room in their head to think about something else but if it's done kind of obviously on a convenient day and just kind of putting it to them in the right way" [Leanne, T3 Junior]

Staff thus introduced the concept of headspace spontaneously without being prompted. In this context, the shared terminology was used to describe the need for more thinking space. This also highlights that the timing and content of the way in which staff were approached to participate in training is important. However,

headspace is less readily defined than the concept of time, as it appeared to mean different things to different people. Claire (T2 Managerial) described a similar concept whereby staff required time to incorporate learning from training into practice:

> "From my experience it's about support and I think that if…you give that person the time, the opportunity to not only do the training but them to put it into practice and they get the outcomes and feel much better about it. There's lots of times where people have gone and asked for training, gone off and done the training and come back and not done anything with it".

> "I think given the pressures on the service, the demand of the referrals that are coming in. It's not always easy to put things into practice".

The Tier 2 team described how they had implemented processes to overcome the difficulties associated with lack of headspace. This involved it being made a requirement for any staff members who had requested to attend training to feedback the learning outcomes to the rest of the team at their monthly meetings.

Time

Time was characterised by the competing priorities staff faced: service pressures in terms of the number of patient consultations, the strict time limits available in which to do this, mandatory Trust training, as well as the overarching concern to help the young people they were seeing. Although training opportunities were prevalent, varied and well received, time was a barrier to staff engagement:

> "…there is quite a lot of training around but it's having the time to do it often" [Joan, T2 Specialised]

> "I suppose fitting in the kind of time to do it in their diary. I know it is only five days but with clinicians being booked up quite far in advance it will have to be kind of planned quite early on I think" [Leanne, T3 Junior]

Despite this, staff were keen to explore the possibility of new alternative treatment approaches, especially those that did not involve lengthy training:

> "I think there is always kind of room for more treatments and things. Particularly with [BA] being so easy to kind of train in, so obviously just five days which is a lot easier to squeeze into someone's diary than doing a diploma for a year or something" [Leanne, T3 Junior]

Effective planning was highlighted as a facilitator to allow staff to partake in the available training opportunities but was weighed against the time burden of the training itself. This cost-benefit analysis by staff led them to make an assessment of their capacity to participate in training, highlighting the significant cross-over with the theme of staff economy. Unsurprisingly, staff economy was often the reason staff gave for difficulties with demands upon their time. Staff referred to the burden of training and noted the competing commitments that they had to balance in their everyday practice. Staff identified Team Managers as key facilitators, particularly in navigating difficulties with staff capacity. The role of the manager was highlighted as central to alleviating these pressures, as Jackie's comment reveals:

> "My concerns are that the staff are overwhelmed and busy and doing all sorts of other things and I'm hoping that the managers have remembered that they are doing this BA training and they've left time and space for it" [Jackie, T3 Psychology/Managerial]

These pressures on staff time due to staff economy have damaged the morale of the team, meaning that any discussion of research was met with a groan and intense questioning of exactly how much time it was going to 'cost' them. Staff chose to highlight how these pressures had led to difficulties finding the time to complete and implement tasks. These demands were replicated in the documentary data (reports and meeting minutes) collected onsite, which described increased workloads and pressure, combined with decreased staffing levels.

Staff economy

This theme was central to the other identified themes (see Figure 5) and was found to be relevant to many of the barriers to trial implementation. In the context of the new working hours, staff economy was characterised by staff changes, decreases in existing staff capacity and staff shortages. Despite a number of new staff being recruited during the study period, staff expressed concern that they "can't see kids quick enough". Staffing shortages were combined with an increased number of referrals to the service:

> "…at the moment, the staffing is quite difficult and the numbers are quite difficult" [Joan, T2 Specialised]

> "…with staff numbers kind of becoming reduced over the previous year and going forward because we do have staff members leaving. Staff members reducing to…part-time hours when they've previously been full-time" [Leanne, T3 Junior]

> "…high staff turnover provides inconsistency for families and the more staff that leave the greater struggle on staff who remain" [Meeting Minutes]

Staff shortages combined with the increased workload were verified in official documentation. The minutes of a Psychology meeting reported "from January psychology staff will be thin on the ground for at least 12 months" and "direct activity has increased". There was a suggestion that these shortages were particularly pertinent in the middle job-grade bandings in Tier 3. In contrast, another Tier 3 staff member believed the number of staff was adequate to meet the service need but highlighted the problem was in individual staff capacity to provide treatment due to staff taking on other competing commitments. Staff articulated there had been a change in the profile of the cases they were seeing in the service, with a trend towards them becoming more severe. The emotional and physical

impact of these pressures was tangible, and observable: staff eating lunch at their desk, if at all; staff making patient notes whilst sat in their cars (to negate the need to return to their base). The stress of staffing issues was never far from the discussion. Staff felt placed in impossible situations and were repeatedly presented with difficult choices:

> "…the group acknowledged it's hard to say no to additional work requests despite no capacity" [Meeting Minutes]

> "[A] lot is outside of our control such as staffing budgets but to remain focused on what we can control- in the sessions with our clients to be the most effective clinicians we can be" [Meeting Minutes]

An additional pressure came from the many calls from concerned parents/carers who noted waiting times and altered appointments as the most common grievances. In contrast, the team also received many messages of thanks, giving weight to one staff's belief that once patients are receiving treatment they are "getting a good deal" (Sarah, T3 Psychology).

As indicated in the non-clinically orientated variance in practice theme, the reported difficulties were anticipated to be of a transitory nature, with Joan (T2 Specialised) stating "we have got big caseloads at the moment that we don't normally have". Staff suggested that this was a direct result of staff economy measures, which had led to them feel overburdened, stressed and under pressure to see increasing numbers of patients in the same allocated time. Various alternate strategies were suggested to overcome the observed difficulties with the new working hours such as improving staff planning, utilising lower grade staff for less specialist tasks, implementing more locality-based working and ensuring new staff appointments fill the skill gaps within the team.

In such a strained environment, research was felt to be a competing responsibility or another worry. One, which did not sit well against its more urgent counterparts:

> "I guess the only issue [with a trial running in the service]…would be if it feels like people are getting taken out of the team again… people will resent that" [Sarah, T3 Psychology]

The value of research was weighed up against the time staff had available in a stretched service. Research was not considered to be a priority in such a stressful environment, despite the stated desire for evidence-based treatment. When Judy (T3 Managerial) was asked if she could foresee any difficulties, she simply said that the biggest barrier to research was "staff, staffing. The staff to do it". Practical suggestions included planning training several months in advance and delivery being spread over several weeks rather than being condensed into one.

> "Just because of the pressures, I have to admit the workers within our team have got a conscience so actually if they're gonna be out of the building for four days they know that actually when they come back they've either got four days of referrals to look at, four days of telephone calls to ring back, four days of appointments to either cancel or rearrange so actually if we do it in two blocks of two…least it would be split nicely in the diaries so they don't feel that it's a huge pressure taken out" [Claire, T2 Managerial]

Staff mentioned the need for support with research projects and again, managers were highlighted as vital in facilitating the implementation of research or training opportunities. Claire (T2 Managerial) stated that it is the manager's role to "stop that merry-go round from going". Others furthered this suggestion by recommending better communication between researchers and managers.

Discussion

This novel approach to sequencing mixed methods to inform RCT design has resulted in the identification of four multifaceted and interlinking themes. The complexity of the findings reflects the intricacies of the setting; unsurprisingly, the implications for the trial design in Stage II are equally complex. In this section, the interpretation of the findings in a broader context will be discussed, followed by the specific implications for the trial design, as well as the strengths and limitations of the ethnography study.

Conducting an ethnography whilst working in the setting was challenging. As an Assistant Psychologist "on placement ", staff already had their preconceptions about me and had assigned me an organisational role. Similar to Cudmore and Sondermeyer (2007) I experienced tensions between my dual role as an 'insider' and 'outsider'. Although such experiences are well documented, I found particular difficulties in identifying what was irregular practice due to not being a *full* insider.

Interpretation of the findings

The narratives discussed in this study point to a hectic team under pressure. During this period of austerity, CAMHS has had to function in an environment where demand frequently outstrips capacity. This ethnography highlights such 'economic' restrictions as central to the other themes that emerged. Staff economy arose as an explanatory factor for the other three themes; representing both an individual barrier in terms of staff's ability to treat patients and a barrier at the managerial/organisational level of the service, due to a lack of available clinicians to treat patients. In light of these resource issues, research and training were understandably not prioritised over the more pressing matters of direct patient care

and administration. This finding aligns with previous research in specialist CAMHS, which found that when a substantial lack of resources were available to the team it affected staff's ability to engage in training opportunities (Edwards et al., 2008). Despite this, the findings indicated a number of conditions that could increase the likelihood of staff becoming involved in research and training. Both time and psychological space were perceived as vitally important to allow staff to make the best use of the opportunities offered. In line with our findings, Edwards et al. (2008) also found release from clinical duties and specific time set aside for learning were key facilitators in this respect. Effective managerial support to prioritise, protect and plan research and training opportunities acted as a key facilitator; allowing staff to overcome difficulties with capacity. Likewise, Edwards and colleagues (2008) found that strong leadership from CAMHS managers enabled staff training and similarly, they also noted this was mediated by financial constraints (Edwards et al., 2008). Previous research has also found resource and capacity constraints affected the therapeutic journey young people took through CAMHS (Turner-Halliday et al., 2014). Although we found indications that this may have been the case, this was outside of the remit of this focused ethnography.

Staff demonstrated good knowledge of NICE guidance for the treatment of depression in children and young people, which was in contrast to previous research that found a lack of awareness of, and poor familiarity with, clinical practice guidelines among physicians (Cabana et al., 1999). Although it was reassuring that clinicians were knowledgeable about evidence-based practice and treatment recommendations, in practice, depression care was not always provided in line with this guidance. There were physical and environmental barriers to optimum delivery

identified during this ethnography and these differed from the individual and social barriers staff encountered following guidelines identified in previous work (Cabana et al., 1999). Although in this study staff were aware when they deviated from best practice, they were prevented from following guidance due to a lack of resources. This appeared to be to the detriment of patients who may not have received care recommended by NICE or have been unnecessarily allocated to a higher Tier of care than required. The lack of staff trained in CBT was surprising in light of the CYP IAPT initiative that was intended to tackle such issues. It also raises questions about the utility of current training mechanisms for practitioners, which may not be sensitive to staff requirements, such as the time necessary for 'headspace'. As in our study, CAMHS clinicians have previously been reported as keen to attend and engage with training programmes (Edwards et al., 2008). This ethnography implies the reality may be more complicated than previously evidenced, and efforts to implement new treatments or training may need to go further than just providing a training course or disseminating appropriate information. This is an important consideration, if BA is to prove efficacious in the future.

As in previous work (Turner-Halliday et al., 2014) we found treatment as usual was 'non-specific', in that it was rarely a named treatment approach such as CBT, and that treatment was case-dependent with CAMHS responding to each individual. During the ethnography staff identified CBT as a gold-standard treatment but this wasn't the treatment necessarily delivered in practice due to resource limitations. Our results suggest a Treatment As Usual (TAU) comparator condition to our novel BA treatment arm would be both feasible and represent high internal validity.

The ethnography has provided knowledge of the structure and processes occurring with the CAMHS team. The informal systems created by staff to share their professional knowledge, were in sharp contrast to the formal organisation of the team. Staff without official psychotherapies training learnt therapeutic skills second hand from colleagues, experimentation or observation. This is at odds with NICE guidance (National Institute for Health and Clinical Excellence, 2005) which recommends psychological therapies should be delivered by therapists who are also trained child and adolescent mental healthcare professionals. This ethnography's findings are also reminiscent of the research summarised by Barlow (1981); like in our study, the clinicians observed by Barlow described themselves as eclectic and learning from clinical experience rather than guided by research findings. Barlow (1981) noted that Clinical Psychologists reported acquiring their techniques through observation of tutors or pupils and using this acquired knowledge to alter their own therapeutic procedures basing subsequent decisions upon 'trial-and-error' in their own clinical practice. Although our ethnography did not indicate clinicians would deviate from the evidence based practice principle in such a manner, the fact that staff in our ethnography considered themselves to be eclectic in selecting their client referents could represent a risk that clinicians may become disenfranchised from the research process. However, most staff observed during the ethnography were found to be open to the concept of research within their team, under the proviso that it did not become another burden in an overwhelmed service. These findings are pertinent to researchers and policy makers, especially in the context of the CYP IAPT Service Improvement Programme and the NHS priorities surrounding research (NHS England, 2017). The observed informal culture of learning, combined with the impact

of the new working hours, lessened opportunities for clinical case discussions and obstructed new knowledge entering the team, which inevitably has an impact on any proposed research.

Ethnography was founded in social anthropology, where historically it was assumed that all members of communities share common cultural beliefs and practices (Savage, 2000). Although staff agreed on many issues, there was a certain degree of polarity present in other areas, which is more in keeping with contemporary commentators and anthropologists who have rejected those earlier theories, instead suggesting individual members of groups may hold vastly differing views. Some staff from non-clinical backgrounds or lower-grade staff were reportedly struggling to work with formal diagnoses in practice, in contrast to their clinically trained counterparts who were comfortable diagnosing and treating patients with a diagnosis. Furthermore, the factors leading to non-clinically orientated variation in practice were also observed to be stratified according to professional background. The impact of staff backgrounds is in line with the findings from many large-scale studies and multi-site trials that have found substantial differences in implementation of interventions across staff types (Kessler and Glasgow, 2011). Yet, although previous research found there was a varied composition of professional disciplines within CAMHS which resulted in differing training needs, our finding differed in the respect that we did not find that these differences were reflected in patient care (Edwards et al., 2008). The staff narratives described the differing viewpoints of staff within the team and represent the difficulties of being amalgamated into multidisciplinary CAMHS teams. This led to power imbalances within the team, which have been previously observed between

individuals in healthcare settings (Savage, 2000). In this case, the ultimate power was seen to be in the hands of the Team Managers who were identified as the individuals who could impose practice change. These findings indicate a need for researchers and subsequently policy makers to account for the intricacies of real life social interactions and relationships within the team and be sensitive to this diversity from the research design stage through to the intervention implementation. Poignantly, the dangers of informal learning by staff that were identified in this ethnography by staff, highlight the risks of research not being relevant to clinicians.

Implications for the trial design

Previous research relating to the benefits of qualitative research in a trials context has been criticised for not clearly articulating how the knowledge gained will be used to inform the trial (Toye et al., 2016). Wells et al. (2012) argue context is vital in order to judge the transferability of the complex intervention that is being evaluated within a RCT. Through the ethnography, a rich understanding of the organisational climate and culture was gained, which was used to inform the trial design of Stage II of the thesis. This ethnographic data, relating to the practice setting in which the trial was delivered, will also assist readers who may consider delivering a BA intervention in other settings in the future. In general, this study shows support for pragmatic trial designs that account for the real-life complexities of clinical practice (Tunis et al., 2003). Previous research in the North East of England (Lewis and Russell, 2013) reported a lack of an opportunity to address staff's concerns and preconceptions prior to the research. This pre-design, focused ethnography offered an opportunity to overcome some of the negative preconceptions associated with research prior to the start of the trial, which helped to foster a more collaborative

attitude between myself, as the ethnographer, and the staff in the CAMHS team. The results from the four themes identified in the ethnography directly informed the protocol of the planned depression trial (see Table 6). The multifaceted and interlinking themes that were identified from the complex setting has led to the impact upon the trial protocol being equally complex. In an attempt to simplify these implications, they have been presented in tabular form and will be discussed in further detail below.

Table 6: Illustration of how the key findings from the Stage I ethnography led to changes in the trial protocol in Stage II (adapted from Kitchen et al., 2017)

<table>
<tr><th>Theme</th><th>Evidence</th><th colspan="3">Implication for Planned Trial</th></tr>
<tr><td rowspan="2">Non-clinically orientated variation in practice and diagnosis</td><td>Differing Staff Backgrounds</td><td rowspan="2">Selection of an appropriate control arm</td><td rowspan="2">Stratified Randomisation by Tier</td><td rowspan="5">Recruitment of a variety of staff from both Tier 2 and Tier 3</td></tr>
<tr><td>Differing Staff Training Experiences</td></tr>
<tr><td>Staff economy</td><td>Staff Turnover/Job Role Fluidity</td><td colspan="2">Recruitment of excess staff/study sites</td></tr>
<tr><td>Non-clinically orientated variation in practice, staff economy and capacity</td><td>Lack of Staff Capacity/Staff Stress</td><td>Five days of training split over several weeks and planned in advance</td><td>Self-selected sample</td></tr>
<tr><td>Capacity</td><td colspan="3">Feedback from Training to Team</td><td rowspan="3">Cluster randomisation may reduce treatment contamination</td></tr>
<tr><td rowspan="2">Non-clinically orientated variation in practice</td><td>Informal Staff Supervision</td><td colspan="2" rowspan="2">Group supervision to facilitate learning</td></tr>
<tr><td>Informal Learning of Therapeutic Skills</td></tr>
<tr><td>Capacity</td><td>Headspace</td><td colspan="2"></td><td>Five days of</td></tr>
</table>

			training split over several weeks and planned in advance
Diagnosis	Lack of Staff Confidence	Use of a structured interview tool to provide a DSM diagnosis by researcher	
	Lack of Diagnoses		
Non-clinically orientated variation in practice* and *staff economy	Speed of Patient Treatment	Reduce treatment delay by recruiting more staff to deliver the intervention and recruitment speed by adding additional study sites	
Diagnosis	Comorbidities	Participant inclusion criteria to include comorbidities	
Diagnosis* and *staff economy	Depression treated in both Tiers	Recruitment across Tier 2 and Tier 3	Stratified Randomisation by Tier
Non-clinically orientated variation in practice	Staff Treatment Preferences and Individual Differences	Perceptions regarding delivery to be explored in qualitative interviews with staff and patients	
Staff economy* and *capacity	Staff and Patient Management	Attendance at regular management meetings	

Many of the barriers to research that were experienced in this ethnography were seen by the CAMHS team as local issues that were irrelevant to the proposed research, and their impact upon the planned research was not previously understood. The data provide comprehensive insights into the usual care pathways surrounding depression in this service, which has enabled the effective allocation of trial resources to the most appropriate sources and allowed refinement of the trial design. Specifically, changes to the service provision during the observation led to internal waiting lists within the service, which would have severely impacted upon the viability of the trial. However, due to the knowledge obtained, protocols could

be implemented to alter the recruitment strategy within the trial, thus limiting the impact of these treatment delays. Another example would be, if the inclusion criteria had excluded comorbidities, 60% of those with depression in the service would have been excluded from Stage II of the research. Thus, a broader inclusion criteria was utilised, which has the added benefit of improving internal validity as the trial participants will be more representative of the patients in the service. Differences observed between Tiers suggested this may be a factor that could affect the results and be a source of bias. This variable could be an important predictor of outcome so could be controlled for in the trial protocol via stratification during the randomisation process. Staff economy and capacity themes suggested close working with service managers to provide forewarning of issues that may impact upon the trial. As such, regular management meetings were planned.

Staff economy, capacity and non-clinically orientated variation in practice themes combined to account for the main barriers to research within the setting. Significant staff turnover led to various difficulties within the service; most notably impacting upon provision of service. Previous research suggests when extensive healthcare restructuring occurs at the same time as the introduction of a clinical intervention it can lead to uncertainty and high staff turnover (Franx et al., 2012); this may translate into slow or reduced recruitment rates in a trial context. This would be particularly disruptive when relying upon training existing CAMHS staff who may then leave the service. This has been accounted for in the RCT in Stage II by training more staff than required, which has the added benefit of sharing the burden of research and assists in maintaining patient recruitment and intervention delivery

in the event of staff dropout. Additional study sites will provide a greater pool of staff to recruit from in the event of low rates of patient or staff uptake.

These findings also raise the question of whether a target-driven service is the most appropriate setting in which to conduct research. The Stage II trial protocol thus has a strong focus upon the feasibility of a trial in this complex setting. Capacity and staff economy themes demonstrate practical arrangements, such as splitting the training across different weeks, which may increase accessibility for busy staff. An additional benefit of this approach would be increased opportunities for headspace.

Supervision is an important component to ensure fidelity to the BA treatment model. Informal supervision was observed in practice, which suggests intervention supervision should be in keeping with a group-learning mechanism. Therefore, a group supervision approach may be suitable and may also meet the requirement for headspace to incorporate learning into practice following the intervention training. However, learning therapeutic skills second-hand may indicate that therapeutic contamination could be an issue. Contamination of the control group can lead to biased estimates of effect size (Hemming et al., 2017). In a trial, cluster randomisation would be one way to account for this. Cluster randomisation involves randomising groups of individuals (i.e., all patients from one CAMHS team) to either the intervention or control conditions. However, this trial design has been criticised for being statistically inefficient compared to trials that use individual randomisation with the same number of participants (Hemming et al., 2017). Individual randomisation is the process of individuals being randomly allocated to receive either an experimental condition or an alternative (such as remaining on a waiting list or standard treatment).

Staff mistrust of diagnoses would not usually present a problem, due to the lack of need for a formal depression diagnosis in routine practice; however, in research projects where a formal diagnosis is often part of the inclusion criteria it represents a barrier to research. It was initially anticipated that the diagnoses provided by the service would be adequate to enrol participants into the Stage II trial, but the ethnography suggests diagnoses are made infrequently and require patients to be transferred to Tier 3 of the service, which leads to treatment delay. While many psychotherapy trials rely upon official diagnoses, the results of this study suggest a more pragmatic choice may be to work outside of a diagnostic criteria. However, this needs to be considered against the need for an accurate and standardised definition of depression across RCTs to compare research findings. It was also anticipated from the initial site meetings that it would be possible to make use of depression classification codes (on patient's electronic records) but due to the lack of diagnoses these were infrequently assigned to patients. As such, a formal diagnosis was judged to be necessary in Stage II of the research to maintain the quality and rigour of the RCT. The lack of formal diagnoses provided by the service represented a practical barrier to research recruitment, which would require additional resource allocation to overcome in order to deploy a researcher-administered diagnostic interview (assigning DSM criteria). This ethnographic study also suggested some staff will find working with clinical diagnoses easier than others due to their previous training and work experiences. An improved understanding of this issue enabled information regarding the rationale for a diagnostic interview to be added to staff study training in Stage II, to reassure staff. A variety of staff were invited to enrol as therapists in the trial and their experiences in relation to treating

young people will be explored qualitatively. This diversity is also important as a first step to exploring whether some staff may be better suited to intervention delivery than others.

Understanding the disparities in patient management was useful in selecting a control arm for the planned trial, ensuring it would also be clinically relevant. During discussions with the team managers at the initial site meetings, CBT was proposed as a potential comparator to BA treatment. The focussed ethnography demonstrated that very few young people in practice received 'pure' CBT (by an adequately trained therapist) so, if CBT had been selected, it would have limited the generalisability of the research to practice because it would not represent routine care. Therefore selecting TAU as a comparator condition may account for the diversity in clinician approaches to depression treatment and preserve the external validity of the trial.

Methodological reflections

There has been a growing interest in and evidence base for, utilising a pre-trial qualitative element to improve trial design. A systematic review identified a growing number of qualitative components being conducted prior to RCTs (Lewin et al., 2009), although few of these used an ethnographic methodology which appears to be well suited to this endeavour. As discussed earlier in the chapter, few of the pre-design components are used to inform the subsequent trial design from conception. Lewin et al (2009) suggest trialists should prioritise qualitative input later in RCT development due to the usual linear model of evaluation. This is in contrast to the MRC guidance (Craig et al., 2008) that emphasises the need for flexibility in that development may be linear, cyclical or staged in another format. This ethnography

has extended the discussion around methods that can be used to inform trial design of context in this respect and added to the published literature in the area (Kitchen et al., 2017). Randomised trials offer a good quality of evidence but may limit the applicability of the research findings to practice. This study's application of sequencing mixed methods, as described in this thesis, challenges current paradigms of method as well as parameters of success. Researchers have suggested clarification of both general and project-specific threats to internal and external validity should be encouraged and considered as a sign of researcher integrity rather than a symbol of investigator ability (Wells et al., 2012). This ethnography recognises the constraints upon researchers in terms of time and resources and suggests a focussed ethnography can limit the misuse of both time and resources within trials by adequately informing the design. This approach fits well with moves towards more pragmatic trial designs (Tunis et al., 2003).

There were some elements of the study methodology that were less successful. The novel 'blended' approach to analysis attempted to reconcile an ethnographic methodology with a focused approach. An approach using multiple coders marries well in a trials context where research teams are the norm. As previously noted, merging different epistemological positions (Dikomitis, 2016) can cause difficulties. Although from the outset of this PhD, the dissonance between the constructionist ethnography and positivist trial was acknowledged, overall the ethnography had more positivist leanings than would traditionally be the case. This caused difficulties when it was suggested that I employ a second coder in order to manage objectivity within the ethnography. As the second coder had not been immersed in the setting and thus had limited understanding of the context of the

transcripts they were analysing, this left me defending my interpretations. This study therefore exemplifies the challenges of working at this interface of social sciences and trials, and has also added to the literature on focused ethnographic fieldwork in clinical settings. In particular the data stress the importance, noted by other researchers, of addressing local problems when designing RCTs (Moore et al., 2015). A focused ethnography may therefore be an important addition to a trialist's toolbox at a developmental stage of trial design.

Strengths and limitations

Mason (2002) highlights a fundamental strength of qualitative research; is its ability to understand context, diversity, nuance and process in a complex and multidimensional social world. For this study, ethnography illuminated how the service, staff discourses and relationships worked and the significance of the meanings they generated. This qualitative approach highlighted a wide array of dimensions of the social world illustrating what Mason (2002) described as the texture and weave of everyday life. A focused ethnography has illuminated pitfalls prior to the trial that site meetings or other methodologies would have failed to access. Although the approach taken was focused, the inductive stance was broad enough to allow for the degree of exploratory inquiry necessary to address the study aims. An unanticipated benefit of using an ethnographic approach was that it enabled bonds to be built with staff prior to the trial in Stage II, which helped to foster successful subsequent working relationships. Ethnographies, even those of a rapid nature, are resource intensive and thus, costly. I would argue that by bridging the gap between research and practice, resources within the trial were better utilised.

A further strength of the ethnography was that there was only one staff member who opted out of the observation and as this was on the final day of data collection this did not impact upon data generation. There were also no refusals to participate in the staff interviews. This indicates that despite initial difficulties integrating into the setting, staff were happy to participate in interviews with me and comfortable with my presence.

The methodological approach may be criticised by ethnographic purists who believe rapid, short-term fieldwork can never adequately integrate the researcher into the setting and thus, does not have the capacity to answer such complex questions. They may raise questions about the validity of relying upon interview data due to criticisms of interviews as a strategy to illuminate beliefs (Mason, 2002). These criticisms are important to address; for example, there were suggestions in one interview that a participant may have been misleading me (due to their reluctance to answer questions). This could lead to doubts about the authenticity of this account when coupled with the same manager's request to review the interview transcripts. The very act of allowing interviewees to review their transcripts may be controversial amongst qualitative researchers (Mason, 2002), as it could potentially enable participants to select socially desirable responses and screen out truthful information they do not wish others to be privy too. In this case, however, no amendments were made to the transcripts. More importantly, whilst interviews may have a more prominent position than is traditionally the case in ethnographic research, the other methods utilised- of observation and documentary analysis- provide alternative accounts through triangulation. As observational and documentary data was collected on an opportunistic or purposive basis, important

information may have been missed but this has to be weighed against the benefits of using a naturalistic approach, which may have been compromised if a more systematic data collection method had been used. Whilst all relevant professions were represented in the participant observation, no Psychiatrists were included in the interview sample as they were not deemed to be key stakeholders, as due to the composition of the CAMHS team they rarely deliver psychological therapy.

Another key limitation was the lack of information obtained on staff's professional training or educational backgrounds; this information was asked for in later interviews, but was not collated in a formal manner nor was such information gathered for staff who were being observed. Such data would have been valuable in strengthening, or refuting, the connections between professional background and behaviour observed. Additionally, all key stakeholders were female, although this is this is reflective of the composition of the CAMHS team as a whole.

The stance and conceptualisation of a single ethnographer has been previously criticised (Cruz and Higginbottom, 2013), however in this ethnography the informed view of the embedded ethnographer was more powerful than an uninvolved researcher. Future research using a focused ethnography would best be analysed by sole or multiple ethnographers based in the setting.

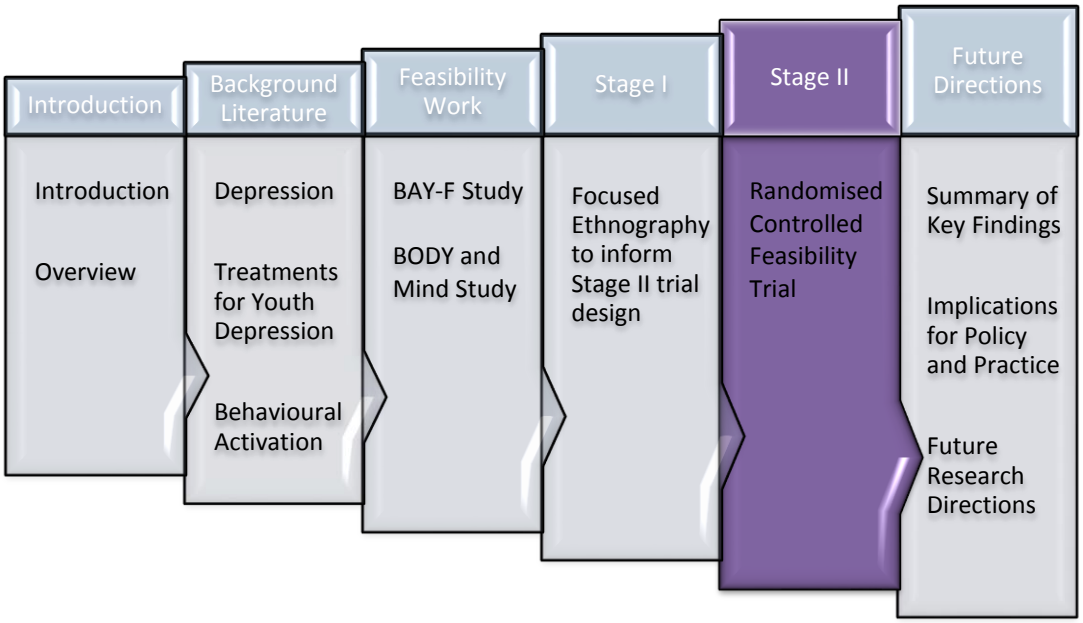
There are inherent limitations in this study, as the views obtained were from professionals within one service, so the findings may reflect a particular local "culture" rather than individual or generalisable perspectives. When reflecting upon my role as an ethnographer, my background in psychology immediately aligned me towards the psychology professionals in the team. Consequently, I may have been skewed to interpret issues from an alternative perspective to nursing staff for

example, which is a deficit of using the conceptual orientation of a single researcher. This was countered through reflexivity and supervision, in order to re-cast the familiar as something novel in order to explore it further (Barber, 2014). As with any qualitative methodology, the results were not intended to be generalisable; however, there are aspects of this research that could be transferable to other settings. The strength of this qualitative approach lies in its ability to allow the complex nature of this particular CAMHS team to be characterised, and to understand the realities of staff experience. This learning has been used to inform the planned trial and similar study sites in Stage II of research and the methodology could be of use in other trials, such as an approach that has been used previously in a multi-site trial to inform researchers of the local differences between sites (US National Insitute for Mental Health Collaborative HIV/Sexually Transmitted Disease Prevention Trial Group, 2007). Although qualitative research is capable of producing well-founded cross-generalities (Mason, 2002), in this case, small differences could affect trial design detrimentally so caution is required. The focused nature of the ethnography may have precluded additional informative information being included in the analysis and the cost of ethnographic studies may be prohibitive. It could be argued that qualitative interviews alone may be a more cost-effective way to obtain similar data in light of these criticisms.

Conclusions

The broader achievement of this study is that it provides a useful case study to illustrate the utility of a focused ethnography to inform the design of a RCT. The pre-design stage enabled adaptions to be made to the protocol for Stage II at a point

when appropriate modification was still possible. Staff knowledge was successfully captured and utilised to create a pragmatic trial protocol that is able to respond to and can be readily implemented into a real world setting. The subsequently adapted trial is undoubtedly more closely aligned to clinical practice, more feasible and more acceptable to staff. This ensures strong external study validity, which is vitally important to satisfy clinicians and policy makers that this novel treatment is credible in the context of the realities of everyday NHS practice. Without the input of the ethnographic methodology, the original trial protocol would not have addressed local barriers to the trial and treatment nor allocated resources effectively and thus, it would have met insurmountable barriers upon implementation. This data has provided important insights into the practical and organisational boundaries into which the intervention would be implemented and situated the trial. The following chapter discusses the RCT that comprises Stage II of this thesis.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Chapter 4 Stage II: A randomised controlled feasibility trial of Behavioural Activation treatment for young people with depression in Child and Adolescent Mental Health Services: Introduction and Methods

Introduction and aims

As discussed in the background literature review (Chapter 1), the paucity of evidence for Behavioural Activation (BA) as a treatment for depression in young people has recently been highlighted in a systematic review of the evidence (Tindall et al., 2017). The systematic review included only ten studies, many of which had methodological limitations, indicating an absence of high quality evidence in the field. Furthermore, none of the included studies were in a UK setting, limiting the relevance of the findings to UK practitioners. The feasibility study that comprises Stage II of this research has been designed as a first step towards addressing some of the identified gaps in the literature. This study represents Medical Research Council (MRC) 'phase II' feasibility research, which aims to examine methodological, procedural and clinical uncertainties (Craig et al., 2008). This Randomised Controlled Trial (RCT) was undertaken to assess whether or not the trial design was appropriate and feasible with regard to patient and staff recruitment and retention, acceptability of the BA intervention and study procedures, as well as adherence to the treatment protocol. This trial comprises the largest component of this thesis, as such it has been separated into five sub-chapters to assist the reader. This first segment

describes the introduction to the study and the methods utilised, the second portion (on page 167) describes the flow of participants throughout the study and the recruitment data gathered. The third instalment (from page 188) discusses primarily the quantitative results (although some contextual qualitative data has been included), which is followed by the fourth sub-chapter (from page 220) on the qualitative analysis. The chapter ends with an integrated discussion of the mixed-methods results and conclusion (from page 274).

There is a lack of consensus on the terminology that should be used to describe the preparatory phase for a trial (O'Cathain et al., 2015). This study has been referred to as a feasibility study due to the aims and objectives of Stage II of this research focusing on whether or not this study can be done, should it be done and if so, how should it be done (Eldridge et al., 2016b). This stance is in line with the Consolidated Standards of Reporting Trials (CONSORT) guidance for pilot/feasibility studies (Eldridge et al., 2016a). Equally this study could be considered to be a pilot study as there is a general consensus that a trial can be considered a pilot when it is estimated to be either too small to detect a minimally important effect size and/or is evaluating an incomplete intervention (Torgerson and Torgerson, 2008). The National Institute for Health Research (NIHR) note feasibility studies should not compare the outcome of interest (National Institute for Health Research, 2017), and although we have cautiously explored the data for the purposes of the thesis this was not an aim of this study. This study is also not consistent with the NIHR's definition of a pilot study as a variety of outcome measures have been deployed and a variety of recruitment methods used with a view to selecting a limited number of these in a future larger pilot trial. Although the utility of accurate description of the

phase of study is acknowledged, this trial reflects the difficulties in assigning the appropriate terminology to complex studies at any stage of research. All other elements of the study are consistent with an NIHR defined feasibility study (National Institute for Health Research, 2017). Eldridge and colleagues (Eldridge et al., 2016b) created a framework to define pilot and feasibility studies using a Delphi survey. They define pilot studies as a subset of feasibility studies, rather than the two being mutually exclusive; the distinctive design component that separates pilots as distinct entities is that they are a small version of a future larger powered trial (Eldridge et al., 2016b). Thus, by adhering to this broader definition we have labelled this RCT as a feasibility study.

The intervention (BA) that this study has been designed to investigate, can be described as a complex intervention according to MRC guidance (Craig et al., 2008). The trial has been designed in line with this guidance which recommends the use of feasibility studies prior to 'phase III' trials. The MRC guidance for complex interventions states that the purpose of the feasibility/pilot stage is to engage in an iterative process of development, feasibility and piloting, evaluation and implementation, testing procedures for acceptability, estimating recruitment/retention rates and calculating appropriate sample sizes.

Principle research aim

To assess the feasibility of a trial of a BA treatment for depression in young people in a Child and Adolescent Mental Health Service (CAMHS) setting.

Research objectives

The study has a number of primary objectives:

1. To assess how many CAMHS sites accept the invitation to participate in research;
2. To assess the best way to approach potential participants by exploring recruitment rates and feedback from participants and clinicians;
3. To determine whether the eligibility criteria for patients were too open or too restrictive by estimating feasibility and recruitment rates;
4. To assess retention of participants by estimating three and six-month follow up rates;
5. To assess the acceptability of the BA intervention to patients and their caregivers through session attendance, qualitative interviews and survey feedback;
6. To assess the acceptability of the BA intervention to CAMHS staff via qualitative interviews.

Secondary objectives:

1. To investigate the completion of questionnaires and outcome measures as methods to measure efficacy of the intervention within a larger trial.
2. To pilot the end of treatment survey designed for this trial.
3. To measure key outcome domains (for completion rates, missing data, estimates, variances and 95% Confidence Intervals (CIs) for the difference between intervention arms) for participants.

Preparatory work

Prior to the conception of the trial, feasibility work was completed which has been summarised earlier in the thesis (Chapter 2). Knowledge gained was combined with

the findings from Stage I of this study (see Chapter 3) to inform the design of the trial protocol and this was amended in light of additional feedback obtained through stakeholder involvement. These preparatory approaches are summarised below, alongside the key aspects of setting up this new study in this setting.

Feasibility work

Extensive feasibility work has influenced the design of this study; for example, the setting of this trial was a direct result of the feasibility issues experienced during two earlier studies in school and primary care settings (see Chapter 2), combined with the findings of the focused ethnography in Stage I (discussed in Chapter 3). Alongside this knowledge, the advent of the Child and Young Person's Improving Access to Psychological Therapies (CYP IAPT) service improvement programme provided a potential framework within which to train and deploy CAMHS practitioners to deliver BA. The presence of a potential mechanism for delivery of any novel treatment is vital to its future implementation in the setting.

Patient and public involvement

There is a moral argument for involving patients and members of the public in health care research, which is founded on ethical and democratic principles (Wilson et al., 2015). There is an additional policy argument, which can be illustrated in guidance issued by the National Health Service (NHS), research funders and governing bodies suggesting public involvement is often a requirement of conducting research (Wilson et al., 2015, Staley, 2009). The added value of Patient and Public Involvement (PPI) was explored in a literature review and report prepared on behalf of INVOLVE, a NIHR national advisory group that promotes and supports greater public involvement in NHS, public health and social care research. They found PPI had a

wide-ranging impact on the research, community organisations, wider community, researchers, PPI members and subsequent research participants (Staley, 2009). Furthermore, meaningful stakeholder involvement can have a beneficial impact upon trial design (Staley, 2009), which may boost study recruitment and improve patient outcomes (Wilson et al., 2015). Crucially, PPI has been found to influence the way research findings have been used to bring about change, such as influencing clinical practice (Staley, 2009). In the context of youth mental health research, like Dan (in Chapter 2), other young people have previously demonstrated a desire to be involved from the conceptualisation of a research project (Mawn et al., 2016). The learning points and recommendations from research conducted by Mawn et al (2016) were followed in terms of facilitating PPI input from young people in a meaningful manner.

Equally, it was important that the views of parents and carers were also considered. A parent, whose children were under the care of CAMHS, was recruited through an advertisement in the waiting area of a community CAMHS team (the site of the focused ethnography). This parent representative provided feedback on the proposed recruitment letter for families, the parent/carer information sheet and other aspects of the study design. This led to changes in the language, content and design of the documents. One example of this was the addition of flow charts to the study information sheets to improve clarity. The study protocol described the intention to make first contact with families via letter; the parent representative felt that this approach was impersonal, formal and would not provide the opportunity for families to ask questions. The parent representative suggested they would prefer to be first approached about the study by their clinician. Therefore, both approaches

were used in the trial and the success of each was explored through the recruitment figures and during the qualitative interviews in order to assess the most suitable recruitment strategy. The parent representative also suggested offering a financial incentive to encourage families to attend the initial information session. In light of this and as an acknowledgement of the time required to complete the assessments, all families were offered a £10 high street voucher for attending research assessment sessions in order to minimise study attrition (up to a maximum of £30 for taking part in the study). Information relating to the financial incentive was added to the information sheets, as advised by INVOLVE (INVOLVE, 2016). However, our reimbursement rates are lower than those offered by INVOLVE who suggest around £25 for a one hour task that does not require pre-preparation; our reduced rate reflects the financial limitations of a PhD and the lower age of the participants.

'Youth Speak', a PPI group of young people aged 14-24 who aim to ensure that the views of young people are embedded into all stages of research development, were consulted. A verbal presentation was made to the group about the proposed study in August 2014, followed by a group exercise focused on developing a study name and poster. Members of the PPI group contributed to the development of a youth-friendly study title ('the BUDDY study': Behavioural Activation for Major Depressive Disorder in Youth) after initial feedback that the scientific title was too complex. A full title may have also increased expectancy effects, as in the scientific title BA is the focus of the study. On several occasions, volunteers from Youth Speak (both male and female aged 14-17) were consulted on an individual basis to provide more in-depth feedback. In particular, they were asked for their thoughts on parental involvement, recruitment methods, diagnostic

feedback, study burden and appropriate reimbursement for participation. The young people's information sheets and consent form were reviewed by young people (of the intended age ranges) in order to ensure the language, structure and design was youth-friendly and easy to understand. One important amendment following this review was changing the term Treatment As Usual (TAU) to 'combined treatment' in the participant study materials to make it as "enticing" as the novel treatment. Another suggestion was to add a photograph of the assessor to the information sheets, as it was reported that this may make people feel more comfortable and counter expectations of what researchers look like. As an additional control, all information sheets had a Flesch Reading Index of above 60, which is the recommended level for plain English for teenagers. The Flesch Reading Index scores range from 0 to 100 with a lower score being more difficult to read; the score is calculated using sentence length and polysyllabic words to determine difficulty (D'Alessandro et al., 2001). It has also been recommend that interview topic guides should be shown to a similar audience to the planned interview participants to elicit feedback (Clough and Nutbrown, 2012). In this case, the topic guides for the qualitative interviews were piloted with young people from Youth Speak. They were asked how it would feel to be asked those questions, whether they understood them and whether there was anything the research team could do to put them at ease. This feedback led to amendments to the interview topic guide.

Site visits

The trial (Stage II of the research) took place directly following Stage I, the focused ethnography. As such, the CAMHS team at one of the study sites (Site One) were familiar with my presence onsite and I continued in my role as an Assistant

Psychologist in order to coordinate the implementation of the trial. As identified in Stage I, additional study sites were necessary to reduce the burden for staff participating in the study as well as to ensure adequate participant recruitment into the study. Two additional sites were identified as they had expressed an interest in participating in the BUDDY study via one of the managers at the original site after hearing about the research. These two sites were acceptable as additional study sites due to their geographical proximity to Site One. Site Two was a large CAMHS team (a similar size to Site One) whereas Site Three was approximately half the size. Only the Tier 2 team from Site Three were included, as Tier 3 of this service was mainly comprised of staff above pay grade 7 (which excluded them from this study as it is part of the study rationale that BA may be able to be disseminated to lower-grade practitioners). After receiving information to suggest the two additional sites were interested in participating in the BUDDY Study, I approached the Team Manager at each site. At Site Two, information relating to the BUDDY study was then presented verbally to the Team Manager and at Site Three a PowerPoint presentation was made to the CAMHS team (as per the manager's request) to invite them to participate. The managers from all three sites approached, agreed to participate. Individual staff members were then given the choice of whether or not to be involved in a personal capacity as discussed below.

Clinician training (June 2015)

Further to the presentations inviting CAMHS teams to be a recruitment site for the BUDDY study itself, PowerPoint presentations were made to Tier 2 staff from each of the three sites to invite individual members of staff to be trained in the BA intervention. Staff were invited to nominate themselves for a place on the BA

training course; all but one of those present agreed to be considered for a place on the BA training (n= 16). Members of Tier 3 staff (pay grades 4-7) were approached individually or via their Team Manager and invited to participate; again all but one member of staff asked, agreed to be considered (n= 18). The two staff (one from Tier 2 and one from Tier 3) who declined the invitation to attend the training, reported this was due to their current commitments to the CYP IAPT training programme therefore they were allocated to provide care in the TAU control arm. From the pool of staff who agreed to be considered for BA training, I selected those who would attend the BA training and those who would provide treatment in the comparator arm. Efforts were made to ensure staff (from pay grades 4-7) in each treatment arm were matched on gender, age, professional background, pay grade and previous training to reduce bias; however, a pragmatic approach was taken in the sense that staff's availability to attend the training was a factor in selection. Higher grade staff (band 8 and above) were not considered for the study training, as one of the primary advantages of BA over other treatment options is the ability for it to be disseminated to lower grade staff. However, this meant all senior staff were assigned to provide TAU, which is a source of bias due to the clustering of staff with greater experience and higher qualifications in the control arm. Staff from the Learning Disabilities (LD) Service were excluded due to the intervention not being suitable for LD patients (as the manual materials require a minimum reading age), as were Band 3 members of staff as they do not hold their own caseloads of patients (so would not be able to provide treatment independently in either study arm).

Behavioural Activation training consisted of a three-day course focussing on the BA model taught by a specialist from the NHS Trust. A participatory learning

approach was used in the training with didactic presentations, role-play, homework and group critiques. Twelve CAMHS practitioners were invited; a total of 10 attended the training, with each study site sending between one and six members of staff on the training. Two invited staff members did not attend the training session; one was unwell and the other was absent (they later reported being too busy to attend). At the end of the training there was a half-day competency assessment, which clinicians had to pass to proceed to providing BA therapy in the trial. If they did not pass the competency assessment, further training was provided as necessary and the amount of extra training was recorded. Competency was assessed using the 'Quality of Behavioural Activation (Short Form)' Measure (as used in a previous trial of COBRA; Richards et al., 2016); the rating scale scores staff on a scale of 0-84. We used a cut-off of ≥40 as an acceptable level of competence (as used in the COBRA trial). There was also a half-day study orientation session provided, which was attended by all staff providing the intervention. In total, the study training was four days long, which was split into two parts and held across two separate weeks, as per the staff preferences in Stage I.

Only one staff member (pay band 4) did not pass the competency assessment (scoring 36 on the Quality of Behavioural Activation scale), further training was provided (three extra half days) but the competency assessment was not re-administered. The reason for this was because the staff responsible for the allocation of patients to clinicians within this site noted the combination of the level of risk inherent in the Tier 3 population, the research diagnosis of depression and the clinician's low pay grade meant no referrals would be received that were appropriate to be allocated to this staff member. This was not an issue at any other sites, as no

other teams put forward a band 4 for the BA training. Therefore, 9 staff (representing all three study sites) progressed as therapists in the BUDDY study.

Modification to the behavioural activation treatment manual

Previous research has highlighted the main benefit of using a manualised approach to treatment within a RCT is to standardise practice and provide clarity on the treatment being provided (Webber, 2014, Olubokun, 2017). A manual may also serve as a link between the structured requirements of research and the clinical needs of practice (Olubokun, 2017). As previously described in Chapter 2, a 12-session BA treatment manual developed and piloted in the USA with 40 young people at an insurance-driven private outpatient mental health clinic (McCauley, 2011) was edited to be suitable for UK-based young people. Content from a manual used in a UK-based trial of BA in adults (Ekers et al., 2011b) was added to the American manual. The subsequently developed manual was used to administer BA over 12 sessions to young people in the two previously mentioned UK-based feasibility studies (see Chapter 2). Qualitative participant, parent and clinician feedback from these studies was later incorporated into the manual. For the purposes of the current study, the adapted manual was condensed so that it could be delivered over eight, rather than 12 sessions to be in keeping with the CAMHS Tier 2 session limit for brief interventions. Rather than the interim outcome measures used in the BODY and Mind study, Routine Outcome Measures (ROMs) were added into each session agenda to bring the study in line with the usual CYP IAPT session monitoring procedures in CAMHS. See Appendix 5 for an overview of the adapted eight-session manual. The manual was further adapted following the results of this trial.

Ethical considerations

Approvals and trial registration

Prior to the ethics application for this feasibility study being submitted for ethical review, it was peer reviewed by a member of staff from Durham University who was independent to the supervisory team. The suggested changes were made to the application which was then submitted to the School of Medicine, Pharmacy and Health Research Ethics Sub-Committee (ref: ESC2/2014/14) and subsequently to the National Research Ethics Committee (ref: 15/NE/0002) and finally to Tees, Esk and Wear Valleys Research and Development (ref: 0360/15) team for approval. See Appendix 6 for approval and insurance documentation. The trial was registered with the ISRCTN Registry, a clinical trial registry recognised by the World Health Organisation (ref: ISRCTN52147450). It is just as important for a feasibility or pilot to be registered with a unique identifier as it is for a definitive trial (Eldridge et al., 2016a). Registration ensures transparency and accountability and ensures all on-going work is in the public domain.

Key amendments

First approach to patients

There were a number of ethical dilemmas to contend with whilst designing this study. Initially I decided that, as the researcher responsible for recruitment, I would make contact with potential participants as soon as they were referred to CAMHS (i.e. before they were seen by a CAMHS clinician); however, this could have been potentially confusing for vulnerable patients and may have led to unnecessary contact with patients not suffering from depression. The study was re-designed to ensure CAMHS staff would always be the first contact for young people entering the service. Similarly, all research contact following recruitment to the study, was

provided by a researcher rather than a healthcare professional. This distinction ensured the clinical relationship between the clinician and young person was not impeded by research-related matters, and that roles remained clear and distinct.

Inclusion/exclusion criteria

When considering the inclusion and exclusion criteria, young people fulfilling the criteria for acute suicidality (defined as more than three self-harm events requiring hospitalisation in the past year) were initially excluded from participating. During site visits, CAMHS staff reported that many of the young people who they routinely see in the service may fulfil these criteria because self-harm/suicidality is so closely linked to depression and often as a precaution a young person would be taken to hospital regardless of the seriousness of the event. It was felt that it was important to ensure the participants in the study were representative of CAMHS usual patients. This needed to be considered against the risks associated with evaluating a new treatment option in a novel population and in light of the tensions between internal and external validity. After due consideration and in line with the pragmatic stance of the trial, young people with suicidal ideation or previous self-harm/suicide attempts were included. As a precaution, young people deemed to require 'urgent' care by their clinician were excluded due to concerns that the administration of the trial would lead to treatment delay.

Consent procedure

The study included patients who were a vulnerable population in terms of their younger age. In light of this, a variety of strategies in addition to those routinely employed by CAMHS were put in place to safeguard participants. Although English legislation does not prevent young people under the age of 16 from consenting to

their own medical treatment, it was acknowledged that these young people may be susceptible to coercion. For this reason, young people aged 12 to 15 were required to provide both written young person assent and parental/carer consent to take part in the study. However, there may still be ethical issues surrounding the role of parents/carers providing consent on the behalf of young people who have the capacity to consent themselves (Royal College of Psychiatrists' Working Party, 2001). Young people aged 16 to 17 were deemed able to consent for themselves (without parental consent) in line with the English Family Law Reform Act 1969, section 8(1) 1969 (Family Law Reform Act, 1969). This stance is further supported in professional guidance published by the British Medical Association (British Medical Association, 2016). As an additional safeguard, as the researcher responsible for taking consent, I was trained in assessment of capacity by an Adolescent Psychiatrist.

Risk procedure

The content of the intervention itself was an important consideration. In any study of a novel treatment, there is a risk that the intervention may not be effective. The previous feasibility work reduced this risk and the clinical setting ensured alternative support was available if necessary. Furthermore, an integral aspect to the CYP IAPT programme is monitoring patient outcomes; one way this is documented is through the use of ROMs, which are administered to young people and their families before, during and following treatment. Failure to progress with BA treatment or any risks could be quickly identified via ROMs or the clinical judgement of trained CAMHS professionals. The need to monitor study participants had to be considered against the potential to create a large study burden for participants. The study was therefore designed to be in keeping with the Caldicott Principles (Department of Health,

2013b); a large amount of the data collected is routinely recorded by CAMHS and additional data collection has been kept to the minimum amount to address the study aims.

Data collection methods

Focus groups were initially considered (over individual interviews) as a qualitative data collection method but they, or even group semi-structured interviews, would not protect or encourage individual's responses (O'Cathain et al., 2015). There would have been ethical concerns around bringing together young people who may otherwise not have known each other's diagnosis of depression, and about asking sensitive questions on the topic in a group setting. Neither would the approach have provided the insight needed into individual perspectives of treatment suitability. Although more time-intensive, an approach based on individual semi-structured interviews was preferred.

Method

Study sample size

Sample size calculations are not always required for pilot/feasibility studies (Thabane et al., 2010). Since this is a feasibility study, a sample size calculation was not performed because the trial is not powered to detect differences (as then it would no longer be a feasibility trial). It is appropriate for the focus of a feasibility/pilot to be an assessment of feasibility, when it is not appropriately powered to assess statistical significance (Thabane et al., 2010). Although, one of the objectives of this feasibility study is to provide estimates of the mean and Standard Deviation (SD) of the effect size of the outcome measures in order to inform the power calculations of a larger trial.

The sample size of a feasibility/pilot study should be guided by it being large enough to provide useful information about the aspects that are being assessed for feasibility (Thabane et al., 2010). Numerical simulation studies suggest estimates of the variance of an outcome metric tend to stabilise at around 30 observations (Lancaster et al., 2004). In terms of qualitative research within a trials setting, sample sizes typically range between 5-20 individuals (O'Cathain et al., 2015). Stage I of this research indicated that given the participant population, we should anticipate a moderate level of attrition. Based on this information, this feasibility study aimed to recruit a minimum of 20 and a maximum of 40 participants. This sample would be large enough to provide sufficient information relating to the practicalities of delivering the intervention, recruitment, uptake and attrition (Torgerson and Torgerson, 2008), whilst also providing adequate recruitment to the qualitative interviews (taking into account those who may refuse to participate) and stable estimates for the outcome measures.

Study population

Participants were drawn from the three study sites' normal intake and caseload of patients during the study recruitment period. Young people were considered to be a study participant at the point of randomisation; all those randomised met the study inclusion criteria below. It is important that the trial sample is representative of the target population (Thabane et al., 2010).

Study inclusion criteria

1. Aged between 12 and 17 years old;
2. Young person to give valid informed assent (if under 16);
3. Young person to give valid informed consent (if 16 or over);

4. Parent/Carer of young person (under 16) to give valid informed consent;
5. Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis of Major Depressive Disorder (MDD) according to the Kiddie-SADS-Present and Lifetime (K-SADS-PL) version.

Exclusion criteria

1. Does not meet the DSM criteria for MDD according to the K-SADS-PL;
2. Presence of significant active substance abuse/dependence;
3. Previous unfavourable response to an adequate regime of Cognitive Behavioural Therapy (CBT) in the past year;
4. Deemed by a clinician to require urgent care.

Design

There were many issues to consider when deciding upon an appropriate research design. The feasibility RCT was designed in line with MRC guidance for complex interventions so that if the results were favourable it could be scaled-up into a phase III effectiveness RCT in the future (Craig et al., 2008). This guidance suggests the staged progression of evidence generation, as this is the early stage of work evaluating BA as a treatment, the feasibility has to be first established before efficacy can be considered. Primarily, the aims of the study dictated the design but ethical considerations, preparatory work, the practicalities of the setting and the resources available also had to be considered.

RCTs have been criticised for lack of applicability to real-world and costs associated with undertaking them (Stephenson and Imrie, 1998). These criticisms are particularly true for explanatory trials, which aim to establish a cause and effect relationship, over 'pragmatic trials' where the focus is upon relevance to practice.

The effect of an intervention in a real-world setting (effectiveness) may differ from an ideal research setting (efficacy). It was important to consider the information the CAMHS service or policy makers require in order to consider implementing novel treatments and to ensure that this study design would suitably inform a larger trial to address those questions. Clinical trials designed to assist healthcare decision makers are known as pragmatic trials (Tunis et al., 2003). It is acknowledged that pragmatic trials may need to employ both qualitative and quantitative methods (Kessler and Glasgow, 2011). Cresswell (2009) described different ways that qualitative and quantitative data collection can be combined, these designs fall broadly under two headings; concurrent and sequential. In sequential designs qualitative and quantitative methods are combined in series, one after the other. In concurrent designs, both methods are conducted alongside each other. In Stage II, methods will be combined concurrently in what Cresswell (2009) terms a 'concurrent triangulation strategy' whereby mixed methods are collected concurrently and then compared.

The BUDDY study is a multi-site, randomised controlled, two-arm, conventional parallel group, unblinded clinical feasibility trial with an embedded qualitative component, comparing individual BA to TAU (see Figure 6). The primary objective of the feasibility study was to identify the likely recruitment, retention, adherence and attrition rates that could be expected in a future trial. It was therefore critical that participants were offered the same treatment options as they would in a future trial to ensure that the recruitment rate was not overestimated. In a larger trial, a control arm is important to see how BA compares to the normal treatment regime, not just whether or not it was helpful treatment option. However,

the primary function of using a control arm in this study was to test out participants' tolerance to randomisation and the acceptability of this particular control treatment option. A cross-over design was not appropriate because the aim of treatment was remission from symptoms of depression so it would not have been possible to provide the two treatments sequentially. It would have also been unethical to use a negative control (i.e. a waiting-list control) in a clinical help-seeking sample because participants would have to wait before being provided with any treatment, which would raise ethical and risk-related problems.

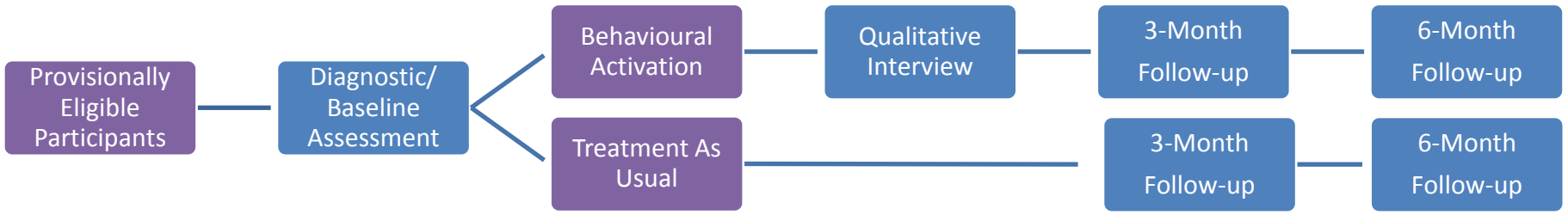


Figure 6: Illustration of the pathways through the trial for participants that meet the study inclusion criteria

Using qualitative methods in partnership with quantitative methods can provide a fuller picture of the matter under investigation (Barber, 2014, Kitchen et al., 2017) and their use has been recommended as an addition to RCT design (Thabane et al., 2010, O'Cathain et al., 2015). The quantitative and qualitative methods selected serve to illuminate differing aspects of the same phenomena under study; that is, the feasibility and acceptability of BA as a treatment option. The quantitative methods were selected to examine participant treatment outcomes, toleration to randomisation and recruitment processes, whereas the qualitative methods explored participant and staff experiences of the processes underlying those outcomes. However, there was no intention to compare qualitative findings between the two treatment groups, which is an approach that has been used in previous trials (Torgerson and Torgerson, 2008); instead, the purpose was to enhance the exploration of the novel treatment arm in-depth in order to provide a multi-dimensional insight to inform the format and content of the intervention in a subsequent larger trial. Often the addition of a qualitative element to a trial is seen only as an adjunct to a mainly quantitative methodology rather than a fundamental aspect of data collection (Mason, 2002). It was of primary importance to understand the CAMHS staff's attitudes and experience of the training and delivery of BA therapy as well as the young people and their caregiver's perspectives of their involvement in the trial and receiving the treatment. Thus, the qualitative data collection was an essential component in order to address the trial aims and objectives. Mixed methodologists have proposed that the shortcomings of quantitative approaches can be addressed by the strengths of qualitative approaches and vice versa. In fact, the two approaches can be complementary (Barber, 2014,

O'Cathain et al., 2015). This means it is well suited to assessing the acceptability and feasibility of a novel treatment approach, in this case BA, from the perspectives of those receiving, supporting and administering the intervention.

One challenge with blending often disparate research paradigms is that it is difficult to combine incommensurate epistemological and ontological assumptions together into a coherent study (Barber, 2014). The central aim of embedding a qualitative component within this feasibility trial was to provide rich, holistic insights into the findings of the trial from a patient, caregiver and staff perspective. Although there is a clear dialogue between researchers regarding the utility of mixed methods, there is less clarity regarding the use of a conceptual or theoretical frameworks to guide inquiry (Evans et al., 2011). Mixed methods is consistent with the world-view of pragmatism (Evans et al., 2011); a pragmatic stance embraces multiple paradigmatic traditions and an alternative philosophical framework that de-emphasises differences in philosophical traditions in order to select a practical and rational approach to mixing methods.

There are two main sources of bias that can impact upon the interpretation of the trial findings; selection bias where the two treatment groups differ in some systematic way, and observer/information bias where there are systematic differences in the way info is being collected for the groups (Kendall, 2003). Bias within a trial can invalidate the study design and as such, make the results less reliable (Akobeng, 2005a); much of this bias can be reduced through the design of the RCT (Akobeng, 2005b).

Randomisation

Random allocation or randomisation is a procedure where individuals are selected for either treatment or control groups entirely by chance (Kim and Skin, 2014). In a RCT these two groups are followed-up to see if there are differences between participant outcomes in the two groups (Kendall, 2003, Akobeng, 2005b). Randomisation seeks to balance out external influences between groups so that the 'true' effect of the intervention is detectable (Stephenson and Imrie, 1998). Randomisation is the best way of controlling for selection bias (and thus, the unbalanced allocation of potential confounding factors), which can lead to inaccurate results (Akobeng, 2005b, Torgerson and Torgerson, 2008). Selection bias occurs when the person responsible for allocating participants to care, consciously or unconsciously decides upon the care given based upon the individual's attributes leading to uneven representation of that characteristic in the two arms. Randomisation controls for selection bias by making it more likely that there will be baseline balancing of known and unknown systematic differences (confounding variables) between intervention groups, and therefore random allocation is important for internal study validity (Akobeng, 2005b, Petrie and Sabin, 2009). Randomisation is superior to non-random methods because it is generally unpredictable and difficult to subvert (Torgerson and Torgerson, 2008).

Simple randomisation was considered for its simplicity and robustness (Torgerson and Torgerson, 2008). A major drawback of this approach is that the two treatment groups rarely end up equal, which was important with such a small sample size. One way to overcome this difficulty is to recruit participants in pairs; 'pairwise randomisation' (note: this is not paired randomisation [i.e. when

participants are matched on particular characteristics]). Once two eligible participants have been recruited; one is randomised to the intervention and one to the control group. This approach would be unethical in a small feasibility study because due to the unpredictable recruitment rate, participants may experience treatment delays whilst waiting for the next participant to enter the study. Blocked randomisation can ensure roughly equal treatment groups (Kendall, 2003, Akobeng, 2005b), which was desirable in this study. However, blocked randomisation can add to the complexity of the process increasing the chances of human error leading to technical bias. In addition, small or repeated block sizes can lead to predictability in non-blinded trials (Kendall, 2003, Kim and Skin, 2014). The primary concern in this study was to achieve roughly numerically balanced trial arms to allow better prediction of treatment resource utilisation.

When all facets were considered, a blocked randomisation approach was selected. Two separate randomisation lists were created; one for Site One and a second for Sites Two and Three (these two geographical locations were amalgamated due to their similarities and the fact that some staff worked across both sites). Each randomisation list incorporated stratification for depression severity (either mild/moderate or severe depression) and Tier (either 2 or 3) to reflect sources of potential bias. Stratification enables balancing (whereas chance may not) of potentially confounding variables between groups, which helps to remove selection bias based upon those known potentially confounding factors (Kendall, 2003, Akobeng, 2005b). Stratification ensures that a potential baseline confounding variable is equally distributed between the two groups (Kendall, 2003). A statistician (independent to the research team) used R software to generate the

four lists of random numbers prior to the start of the study (two lists for each 'site'; one representing depression severity and one the Tier). These two lists were subsequently incorporated into a master list for each site, which were stored as different tabs on one master spreadsheet. The block size was concealed from the study team and only revealed after recruitment had ended. As each patient was accepted into the trial (at the point when they provided consent at the diagnostic interview stage) they were assigned to the next consecutive number on one of the two random digit lists depending upon the severity of their depression and Tier; if the number they were assigned was odd they were allocated to the BA treatment arm and if it was even they were allocated to the control arm. It should be noted, however, that 'random' numbers generated by a computer are not truly random; they are pseudo-random because a computer utilises deterministic mechanisms, such as clock speed to produce random numbers, so prediction is technically possible (Torgerson and Torgerson, 2008).

Allocation concealment is a technique to prevent selection bias whereby the researcher is blinded to the method of randomisation so that they are unable to predict which treatment group the participant will be allocated to (Kim and Skin, 2014). The allocation sequence was concealed from the researcher responsible for enrolling and assessing participants, allocation was not revealed until the assessor had provided participant details to the secretary. Telephone (sometimes known as 'distance') randomisation was used, where a secretary from the study site telephoned an otherwise uninvolved secretary at the university who held the randomisation list (two volunteers undertook this role). Telephone randomisation is the preferred method for concealing allocation in RCTs as it means the investigator

who recruits the participant is uninvolved in the process of allocation (Akobeng, 2005b). The secretary at the study site was provided with the relevant details for the new participant to be randomised and then telephoned the university secretary. The university secretary enrolled and issued the treatment allocation that assigned participants to the interventions. I then received an email from the university secretary with the allocation information so I could inform the clinical team and manually assign the participant to an appropriate clinician for that treatment arm. This remote approach is preferable over more traditional methods such as sequentially numbered sealed envelopes, which can be opened once participants have agreed to enter the study. These envelopes can be easily tampered with so may lead to selection effects (Torgerson and Torgerson, 2008). It is more rigorous to remove the researcher responsible for collecting the outcome measures from the process of randomisation because it reduces bias. This was a practical option in light of the resource restraints. Electronic rather than paper randomisation lists are preferable due to the likelihood of improved data entry and storage (Kim and Skin, 2014).

Blinding

Within RCTs, there is always the risk that participants, clinicians or assessors have preconceptions relating to the treatments offered in the study; this can lead to intentional or unintentional bias during the treatment or collection of outcome measures (Akobeng, 2005b). Blinding is the term given to the process of ensuring that researchers, participants (and their families) and/or clinicians (and in some cases statisticians) are unaware of, or 'blinded' to, the intervention to which the participant has been allocated (Petrie and Sabin, 2009, Kim and Skin, 2014). The

purpose of blinding within an RCT is to avoid bias during the completion of outcome measures, analysis and/or interpretation of results due to participants (i.e. treatment recipients, parents, clinicians, researchers, statisticians) providing responses that they believe are desirable. For example, if the researcher responsible for completing a diagnostic assessment believes a positive result in favour of the novel treatment may make publication more likely, they may (consciously or unconsciously) complete the assessments for those in the novel treatment arm more positively than the control arm.

Although it was possible to remove the researcher responsible for conducting follow-up assessments from the randomisation process, as the sole researcher on the trial I was unable to be blinded after participant assignment to intervention groups. Clinicians were unable to be blinded due to the need for them to be trained and deliver the prescribed intervention and in order to ensure patient records were accurate. Patients and caregivers were also not able to be blinded as it would have been unethical and they were required to provide informed consent to participate. This is an acceptable approach for complex interventions, where it is often unfeasible to blind certain people to allocation (Eldridge et al., 2016a). A mix of clinician, parent and self-rated measures were included, most outcome measures were highly structured reducing the opportunity for bias.

Data collection timetable

Recruitment was scheduled between March 2015 to March 2016. Those randomised were followed up at three and six months from the date of randomisation. At three months, follow-up requests were sent two weeks prior to the follow-up due date (and assessments were completed at the earliest opportunity) and reminder letters

continued until four and a half months post-baseline (the halfway point between three and six-month follow-up). Six-month follow-up requests were sent two weeks prior to the due date and continued until seven and a half months post-baseline. Any responses received outside of this active follow-up period were still followed up. Qualitative interviews with participants who had received BA treatment (and their parents/carers) were offered at treatment completion; this was either at three-month follow-up or a separate appointment held after their three-month follow-up session (if they had not completed BA treatment by the three-month follow-up stage). Qualitative interviews with clinicians took place during or after clinicians were administering BA so that staff had a varied caseload of patients at various stages of treatment on which to reflect.

Recruitment

Study participants were sourced from the pool of young people referred to CAMHS or currently on staff caseloads during the study recruitment period. Young people attended CAMHS and were assessed by their clinician in the usual manner, without involvement from the researcher. They were not approached to participate in the study until they had had at least one appointment with a CAMHS clinician. The first step in identifying eligible participants (those meeting the inclusion criteria above) was to invite those who may be eligible to hear more about the study, and, if they wished to participate, ask them to complete further assessments. As such, a provisional eligibility criterion was developed to provide a simple way to screen for potential participants in the study. Young people aged 12 to 17 years old with clinically significant depressive symptoms (as assessed by parent/carer, child or clinician) who were not receiving treatment for these symptoms were considered to

be provisionally eligible. Clinicians were also asked not to approach patients who were assigned to the LD team or required urgent care (this was also the case with researcher-led approaches). Three different approaches were utilised in parallel to determine provisional eligibility;

- A case note review;
- A study poster;
- Clinician approach.

Case note review

The electronic case notes of patients currently allocated to clinicians at the participating CAMHS sites were reviewed using the Trust's electronic records system (PARIS). Patient notes had to be accessed via a 'case manager' platform and each study site was hosted on a distinct platform within PARIS (where each Tier had to be accessed separately). Utilising the case manager platforms, each member of staff aligned to that Tier could be viewed and the patients on that staff member's caseload could be accessed via a drop down list. The case note review started with the first staff member's caseload and proceeded down the list of staff members in that Tier (staff were displayed in alphabetical order by surname); reviewing each staff member's caseload in turn. Young people's case notes were displayed in the same way and were also accessed in alphabetical order. Each patient screened was recorded in the study recruitment spreadsheet. The case note review continued during the participant recruitment period (when time was available).

When a young person was identified as provisionally eligible, the family were contacted via post. Provisionally eligible families were sent an information pack (see Appendix 7), including an invitation letter, 'consent-to-contact' letter and study

information sheet (information sheets were printed from the relevant sections of the parental, or young person [either aged 12-15 or 16-17] baseline booklets) and a pre-paid addressed return envelope. Families were asked to read the information sheets (the pack included a parent/carer version and an age-appropriate version for the young person) and return the consent-to-contact form to indicate whether or not they would like to hear more about the study by attending an information session (potentially progressing to a diagnostic interview to assess their suitability for the trial). Those that declined further information were not contacted again and those that were happy to hear more about the study were sent an appointment letter for an information session. Young people were encouraged to bring a parent/carer to these appointments, even if they were aged over 15.

Poster

A poster (see Appendix 8) was displayed in the waiting rooms of each participating CAMHS team advertising the study (and the provisionally eligibility criteria); Site Two and Three displayed one large (A0) poster and in Site One, due to the design of the waiting area two large posters were displayed. In all cases, the posters were accompanied by business cards with the study name and researcher contact details on. Patients and their families could use these contact details to directly refer themselves into the study. When families made contact (via telephone or email), their provisional eligibility was assessed by accessing their case notes using PARIS. Families were then informed (via telephone or email) if they were provisionally eligible for the BUDDY study; those that were ineligible were informed over the phone and were not contacted again. Those that were provisionally eligible received information sheets (parent/carer and age-appropriate young person version) and an

appointment letter to attend an information session (and potentially a diagnostic interview).

Clinician approach

The final way potential participants were referred into the BUDDY study was by their CAMHS clinician; this could occur in several different ways. Patients may have been approached during a routine appointment by their clinician (if the clinician judged them to be provisionally eligible) where they would be provided with basic verbal information relating to the study and the clinician would seek permission for researcher contact and ask if they were happy to receive further information (verbal consent-to-contact). If this was the case, families were sent the study information sheets and appointment letter for an information session (as above in the poster recruitment approach). Similarly, a clinician may have identified the young person during a routine appointment but the clinician may not have approached them. Another option would be that clinicians may have identified a patient as provisionally eligible based upon information in a referral (i.e., prior to seeing the patient) or reviewed their own caseload (for patients they had previously seen). In cases where a verbal consent-to-contact had not been received, an information pack (as in the case note review) would be sent to the family by post and they would be asked to return the paper consent-to-contact form. Only families that indicated they were happy to be contacted would be invited to an information session (and possible diagnostic interview).

Clinicians were informed and reminded about the study through information presented at their team meetings, as well as study eligibility criteria that was circulated via emails from the Team Managers on a regular basis. In response to

repeated requests from staff for clarification of the eligibility criteria, posters (A4) were displayed in staff offices (see Appendix 8) with an overview of the provisional eligibility criteria and guidance on how to refer patients into the BUDDY study. The colours on these posters were changed half-way through recruitment to ensure they continued to capture the staff's attention. I also regularly fed back recruitment figures to the CAMHS teams at staff meetings in order to raise the profile of the study.

Measures used

According to MRC guidance, a crucial aspect of the design of an evaluation is the choice of outcome measures (Craig et al., 2008). A variety of evidence-based routine and research measures were selected (see Table 7 below for the time points each was collected). The selection of outcome measures was informed by the feasibility and preparatory work for the BUDDY study and based upon the need to measure clinically relevant outcome measures, provide a research DSM diagnosis and limit the burden upon participants. At diagnostic interview, measures were taken to confirm study eligibility; this data was considered as the baseline measures for those progressing to enter the study. Young people who were randomised were then followed-up at three months (post-randomisation) where an exit interview was completed to repeat baseline measures and at six-month follow-up a telephone interview was completed to repeat selected outcome measures. Regular ROMs were also collected at each treatment session in both arms. The outcome measures used have been described in further detail below.

Table 7: Time-points outcome measures administered across both study arms

	Baseline	Three-month follow-up	Six-month follow-up
K-SADS-PL[a]	•	•	
MFQ-C[b]	•	•	•
MFQ-P[c]	•	•	•
RSE [d]	•	•	•
CGAS[e]	•	•	
BADS[f]	•	•	•
End of Treatment Survey			•

[a] Kiddie-SADS-Present and Lifetime Version (K-SADS-PL) provides DSM-IV diagnostic criteria for MDD
[b] Mood and Feelings Questionnaire: Long Version Child Self-Report (MFQ-C)
[c] Mood and Feelings Questionnaire: Long Version Parent Self-Report (MFQ-P)
[d] Rosenberg Self-Esteem Scale (RSE)
[e] Children's Global Assessment Scale (CGAS)
[f] Behavioral Activation for Depression Scale: Short Form (BADS)

Diagnostic interview

A depression diagnosis (MDD DSM-IV) was confirmed using the affective disorders schedule from the K-SADS-PL at baseline (diagnostic interview) and three-month follow-up. The K-SADS-PL is a semi-structured interview for children and their parents, which assesses both current and past diagnoses (Kaufman et al., 1997). From the information provided during the assessment it is possible to assign severity ratings to the young person's symptomology (see severity criteria in Appendix 9). The advantage of the K-SADS-PL is that it provides algorithms for assigning DSM-III and DSM-IV diagnoses (American Psychiatric Association, 1987, 1994). A standardised diagnostic interview was used due to the criticisms of previous work in the field (Tindall et al., 2017), where young people were recruited into studies who had not received a diagnosis of depression at baseline. The K-SADS-PL has also been used in other BA RCTs involving young people (Ritschel et al., 2016), so it provides a comparable outcome measure with other literature. A structured diagnostic interview was also selected to ensure replicability and reliability. That said, it should

be noted that the purpose of diagnosing depression was for research purposes so, although the diagnostic information was recorded on patient's electronic care records (via PARIS), it was not explicitly fed back to families. The rationale for this was due to the findings of Stage I that indicated diagnoses were not usually made in the service. The K-SADS-PL has been described as the 'gold standard' to diagnose depression (Wood et al., 1995). The 'present and lifetime' version has been purported to improve diagnostic reliability when compared to previous versions and because it allows the researcher the flexibility to alter the probes to suit the developmental level of the child; this was important when including young people aged 12 to 17 years old. In adolescents, the K-SADS-PL is designed to be administered to the young person first and then their caregiver as a secondary source of information. This design is supported by findings that children provide more accurate information about their mental state than their parents (Barrett et al., 1991). Clinical judgement was used to resolve any discrepancies between child and parental reports.

The structure of the K-SADS-PL involves completing:

1. An unstructured introductory interview (10 to 15 minutes) with each informant separately.
2. A diagnostic screening interview (5 to 10 minutes) with each informant separately.
3. The supplement completion checklist (3-5 minutes) with each informant separately.
4. The appropriate diagnostic supplements (the affective disorders schedule in this case) with each informant separately.

5. The summary lifetime diagnoses checklist and the Children's Global Assessment Scale (CGAS; 5-10 minutes) after synthesising data and resolving any discrepancies.

In total the instrument takes between 35 and 75 minutes to administer per informant (Kaufman et al., 1997). Young people were eligible for the study if they met the DSM (III or IV) criteria for MDD on the affective disorders supplement of the K-SADS-PL.

Self-report measures

The Mood and Feelings Questionnaire (MFQ) long version is a depression scale aligned to DSM-III-R criteria for MDD (Angold et al., 1987). There is a 33-item self-rated version for children (MFQ-C) and a 34-item parallel version for parents to rate their child (MFQ-P). The self-report version MFQ demonstrated acceptable reliability in adolescent psychiatric outpatients aged 10 to 19 years old (Wood et al., 1995). The questionnaire asks respondents to rate symptoms (over the past two weeks) as true (scoring two), sometimes true (scoring 1) or not true (scoring zero); totalling a maximum score of 64. The higher the score, the more severe the low mood; we used the cut-off of ≥27 on the child version and ≥21 on the parental version to indicate a positive screen for depression.

The Rosenberg Self-Esteem Scale (RSE) is a 10-item self-report measure for self-esteem where young people are asked to rate items on a four-point Likert scale from strongly agree to strongly disagree (Rosenberg, 1965). The higher the score, the higher the self-esteem; a cut-off of ≤14 indicates low self-esteem.

The Behavioural Activation for Depression Scale (BADS) has been used to monitor self-reported activity, avoidance and impairment over the past week

(Manos et al., 2011). It consists of 9 questions, each rated on a seven-point scale ranging from 0 (not at all) to 6 (completely); higher scores represent increased activation. This scale has not been validated in an adolescent population but was selected due to an absence of alternative measures.

An end of treatment survey comprising of fixed and open-ended questions, was administered to explore the acceptability of the study and treatment options with participants and their caregivers, in both treatment arms. This survey was designed specifically to evaluate this study and was not a ROM in the CAMHS service.

The CYP IAPT programme mandates the collection of measures of assessment, review and discharge and frequent session-by-session measures designed to help support discussion and monitor progress towards treatment goals (Department of Health, 2013a, Wolpert et al., 2012). Routinely collected outcome measures were obtained via PARIS; young people were asked to complete the Revised Children's Anxiety and Depression Scale to monitor depressive symptoms and the Strengths and Difficulties Questionnaire to provide information on emotional, conduct, attention and peer relationship difficulties. The Health of the Nation Outcome Scale Children and Adolescents was conducted by clinicians as a brief metric of other psychiatric symptoms. Guidelines issued for CYP IAPT advise at least one ROM should be completed per session (Wolpert et al., 2012); these measures were especially useful to monitor patients who withdrew or dropped out of treatment. The acceptability of each treatment arm was evaluated by the Commission for Health Improvement, a routinely collected experience of service questionnaire given at final treatment session by the clinician to patients.

To assist with estimating potential recruitment rates in a larger trial, the number of eligible young people, the number agreeing to diagnostic interview, those diagnosed with depression and those agreeing to proceed into the trial were recorded as per good practice (Eldridge et al., 2016a). Significant (i.e. drop out) or adverse events and treatment session descriptions from PARIS were also noted.

Treatment content

The comparison condition (TAU) represents standard care in CAMHS; participants receiving TAU received treatments deemed appropriate by their CAMHS professional; there were no restrictions, protocol or extra training given. The treatment participants received was recorded by their clinician using the usual mechanism on PARIS (a drop-down box where a variety of treatment approaches can be selected). Treatment as usual was provided by clinicians who had not been trained in the BA intervention. Clinicians in the BA arm used the manual to implement BA for eight sessions (see Appendix 5 for an overview of manual session content). Participants were considered to have received BA if they received one or more treatment sessions (a criterion decided by the BA expert). The reason for this was due to the treatment rationale and model were covered during BA session 1. Clinicians were asked to restrict other psychotherapies whilst delivering the BA intervention but were told they could provide any additional psychotherapy as deemed necessary following delivery of BA (this was recorded on PARIS). Sessions of BA are designed to be delivered face-to-face, spaced about one week apart and last around one hour. Staff delivering BA attended monthly group supervision sessions and had access to individual telephone supervision with a BA expert as and when staff required it. During the trial, treatment fidelity to the BA model was assessed in

a randomly selected 10% (decided using a random number generator and a matrix) of BA treatment sessions that were digitally recorded, using a digital audio recording device approved by the Trust. These recordings were coded by the BA trainer using a fidelity measure, which was used in the BODY and Mind study in Chapter 2 and a previous BA trial (Ekers et al., 2011b). In both arms, clinicians were advised of the outcomes of any research assessments via PARIS. Therapists provided either BA or TAU within the study.

Procedure

Information session

Families of those who were deemed to be provisionally eligible and who agreed to hear more about the study were asked to attend an information session. The appointments were held onsite at their local CAMHS site in a private treatment room. Any families who refused this invitation were noted. Families were provided with a verbal summary of the study (additional copies of the paper information sheets were also available) and families were given the opportunity to ask any questions. Families would then be asked if they would like to take part in the BUDDY study and were provided with a paper consent form; young people aged 16 and 17 were asked to completed an informed consent form and those aged 15 and under to complete an informed assent form as well as a parental informed consent form (see Appendix 7). If consent was provided, young people (and parents/carers if present) proceeded to a diagnostic interview (K-SADS-PL) during the same meeting. Those that did not provide consent continued their care as normal within CAMHS and took no further part in the study. Each family attending the information sessions (even if they did not progress to the diagnostic interview) received £10 in vouchers.

Diagnostic interview

Families who provided consent at the end of the information session progressed to the diagnostic interview during the same appointment where the K-SADS-PL, MFQ-C, MFQ-P (if aged 15 and under), RSE, CGAS and BADS were administered. The results of these assessments were compared against the study inclusion and exclusion criteria. At the end of the diagnostic interview families were informed that they would receive a letter to indicate whether or not they were suitable to take part and if so, which treatment they had been allocated to.

Following this appointment, a secretary from the CAMHS team was asked to randomise the patient by telephoning the independent secretaries who held the randomisation lists. The CAMHS secretary provided the name, Tier, severity of depression and study site. Participants were be subsequently allocated to BA or TAU; on some occasions this involved changing their clinician if they have already been allocated to a practitioner by the service at the time of randomisation. A letter was written following randomisation to inform participant's general practitioners of their participation in the study.

Exit interview

The structured diagnostic interview (K-SADS-PL) was repeated three-months after the diagnostic interview. Participants were reminded of their right not to participate in case they wished to withdraw their consent. Remission from depression was defined as no longer meeting the criteria for MDD according to the K-SADS-PL. The MFQ-C (and MFQ-P if necessary), RSE and BADS were repeated and the end of treatment survey was also administered at this point to young people and the

parents/carers of those under 16 (see Appendix 10 for the follow-up workbooks). Families were given £10 in vouchers for attending.

Qualitative interviews

All participants in the BA treatment arm (and their caregivers) were invited to attend a semi-structured in-depth qualitative interview. Data collection continued until no similar issues were raised, a concept called data saturation. Young people were offered the option of an interview alone or with a parent/carer present. If they had completed BA treatment at the three-month exit interview the qualitative interview was held at the same appointment; if not, it was held during a separate appointment at a later date (where they received an additional £10). This interview followed a topic guide (see Appendix 11) of semi-structured, open-ended questions where interviewees were encouraged to talk about the topics of most importance to them. Exploring topics of interest to the participants enables a greater understanding of the outcomes that patients deem most relevant, rather than those of interest to the researcher (Torgerson and Torgerson, 2008). The topic guide was designed to be open but with prompts designed to elicit additional information on both views on the trial and wider experiences, both positive and negative.

All staff responsible for delivering the BA intervention in the study were also asked to attend a similar interview (see Topic Guide in Appendix 11). Staff were provided with a paper information sheet and consent was sought at the time of the interview (see Appendix 12). The findings will inform the refinement of the treatment manual and intervention following the trial. All interviews took place in the staff or young person's usual CAMHS site, in a private room.

Telephone follow-up

The MFQ has been reported to be a useful measure of clinical remission in adolescent psychiatric outpatients (Wood et al., 1995). Six-months after the post-diagnostic interview, all participants received a telephone call to re-administer the MFQ(s) and RSE to assess medium-term outcomes. This took approximately 15 minutes and marked the end of study involvement.

Dissemination

A lay summary of the results was sent to all participants and clinicians who participated in the trial (see Appendix 13). Service team managers were also written to and a PowerPoint presentation was offered to disseminate the results to the wider team.

Data management

Paper data was stored in a de-identified format (using unique codes) in a locked filing cabinet onsite at the University. Electronic patient data were stored in a secure file on the university computer, which only the research team has access to. A backup will be kept on a password-protected encrypted data stick. Data will be destroyed securely after a period of 10 years.

Data from the trial were entered and stored on Excel spreadsheets. Each row of data corresponded to a different individual in the study and each column to a variable (repeated at different time points); numerical codes were assigned to categorical data where necessary (i.e., 1 for yes and 0 for no) and missing data were indicated with a full stop.

Data analysis

Quantitative data analysis

The quantitative results are presented following the Consolidate Standards of Reporting Trials (CONSORT) guidelines for randomised pilot and feasibility trials (Eldridge et al., 2016a). The CONSORT guidelines aim to improve the transparency and quality of reporting of RCTs. The extension to the 2010 guideline focuses on advice for external pilot and feasibility trials, where effectiveness or efficacy is not the primary focus.

Quantitative data were exported from Excel into STATA (version 13.1, StataCorp), a specialist statistical package, to carry out analyses. Quantitative analyses with inferential statistics are presented for the following numerical outcome variables: MFQ-C, MFQ-P, RSE, CGAS, and categorical depression status on the K-SADS-PL. Descriptive statistics only have been included for the BADS, the categorical severity ratings on the K-SADS-PL and the end of treatment survey. For the MFQ-C and MFQ-P variables, higher scores represent lower mood; therefore, a negative gradient over time represents improvement. For the RSE and CGAS variables, higher scores indicate higher self-esteem and functioning respectively; therefore a positive gradient represents improvement over time. In terms of presenting data for the clinical endpoints, mean (SD) for continuous outcomes and raw count (%) for categorical variables are reported.

The validity of the conclusions drawn from the data relies upon the appropriate analysis being conducted and a requirement that the underlying assumptions inherent in the proposed statistical analysis are satisfied (Petrie and Sabin, 2009). Data were examined in order to determine whether parametric or non-

parametric tests were appropriate. A one-way ANOVA (parametric) or Kruskal-Wallis (non-parametric) test would have been used in order to explore the comparability of the patient characteristics between treatment groups at baseline and investigate any differences in those who have and have not dropped out at follow-up. For the K-SADS-PL depression status data, a binary logistic regression was used to assess whether the odds of remission were greater in the BA arm than the TAU arm. For the MFQ-C, RSE and CGAS data, effect sizes for the BA versus TAU were calculated via the 'e-size' command of STATA. The exception to this is where the missing outcomes were multiply imputed. In this case, the effect sizes were estimated via recombining the results of linear regressions for the imputed datasets using the 'mi estimate' syntax in STATA. Calculation of effect sizes is not strictly appropriate for feasibility studies; as such, this was not planned in the original protocol. However, upon reflection and for the purposes of this thesis, the methods that would be used in a larger trial have been mimicked in a post-hoc reflective analysis. For outcomes on a continuous scale, a commonly used effect scale for group comparisons is Cohen's d, defined as the difference between two means divided by the pooled standard deviation of those means (Cohen, 1992). Cohen (1992) suggests a value of 0.2, or less, is indicative of a small effect, approximately 0.5 a medium effect and around 0.8 a large effect. Cohen's d was selected to report effect sizes over Hedges g as Hedges is typically used in samples smaller than 20. The size of the group difference is the key statistic, which will be presented with CIs as a measure of the precision with which this has been estimated. The CIs enable consideration of the range of possible values that could be potentially consistent with the data and thus permit assessment of whether effects within this range of magnitudes may be of clinical importance

(Rutter et al., 2008, Akobeng, 2005b). Typically, any estimates of effects using participant outcomes as they are likely to be measured in a future definitive RCT would be reported as estimates with 95% CIs without p-values because feasibility/pilot trials are not powered for testing hypotheses about effectiveness (Eldridge et al., 2016a). In this case, results have been presented with p-values, bearing in mind the risk of 'fishing' for significance (via multiple tests and outcomes) and the probable lack of power in a feasibility study. A p-value can be thought of as the probability that the observed difference (or one more extreme) between the two treatment groups occurred solely by chance (Akobeng, 2005b).

Missing data, even at this feasibility stage, is a major threat to the validity of the results of the trial and represents a challenge in how to address this at this stage and in a larger trial (Akobeng, 2005b). Although it is common in RCTs to have missing data at follow-up due to drop-out, unless this data is missing completely at random it could be a source of bias of treatment effect. As such, extensive efforts were made to follow-up families by offering a financial incentive, reminder letters and rearranging missed appointments. Participants lost to attrition could not be included in the descriptive statistics; however, missing data has been accounted for in some of the exploratory statistical analyses.

There are various ways to deal with missing data when it is analysed, such as conducting 'Per Protocol' (PP) or on-treatment analyses (where only those who receive treatment as detailed in the protocol are included) or Intention-To-Treat (ITT) analyses where all randomised participants are included. A meta-epidemiological study, based on a collection of meta-analyses of RCTs, found excluding participants with missing data from the analyses can bias results; with the

degree and direction of such bias being unpredictable (Nüesch et al., 2009). When participants who were randomised are excluded from the analysis it can defeat the purpose of random allocation, thus leading to bias as we can no longer be confident that important baseline prognostic factors between the two groups are similar (Akobeng, 2005b). Per protocol or on-treatment analyses are therefore not recommended, as they often lead to biased treatment comparisons (Petrie and Sabin, 2009). Therefore, no PP analyses have been undertaken.

An ITT analysis has been conducted for all participant randomised where data is available. With an ITT analysis you can account for the missing data in several ways, such as by using the 'Last Observation Carried Forward' (LOCF) or by using a statistical process called Multiple Imputation (MI) to work out a plausible missing value. Here ITT analyses have been conducted, where all participants assigned to a treatment group at randomisation are analysed in that group regardless of whether they followed the treatment regime. Two methods were used to insert the missing values; firstly LOCF and secondly MI. The LOCF approach simply uses the last data point observed and inputs it to the next data point (i.e., where baseline data has been collected but there is no three-month follow-up data, the baseline score would be used at the three-month time point). This approach assumes that the missing value is equal to the last observation made which can bias results in either direction as it fails to reflect the uncertainty around missing values (Nüesch et al., 2009). To address some of the deficits of LOCF, MI was also used, which allows for uncertainty around missing data by creating many imputed data sets sampled from predictive distributions modelled on the available set of observations, rather than just one replaced value (Sterne et al., 2009).

All statistical analyses using STATA were completed alongside one of my supervisors (Paul Tiffin), as becoming fully competent in the design and application of advanced statistical techniques (such as MI) was beyond the remit of this PhD. In a larger trial where additional resources were available, a statistician would be consulted to design and implement a data analysis plan. Four of the included Figures (Figures 18-21) were produced by my supervisor's assistant, from STATA using the package 'coefplot' to my specifications.

Qualitative data analysis

Qualitative interviews were audio recorded and transcribed verbatim. Identifying information was then removed from the transcripts to anonymise the data. Pseudonyms were given to preserve anonymity and assist the reader in identifying the speaker. The qualitative analysis focused on remaining true to the participants' voices and developing responses to the research questions, rather than using a methodology that relies more heavily on researcher interpretations. An inductive approach to qualitative data analysis was utilised, in which meanings emerged from the data through iterative exploration of the data set, using a thematic analysis approach according to the principles of Braun and Clarke (2006). Thematic analysis is considered to be an appropriate approach to analysing qualitative data in the context of a feasibility trial (O'Cathain et al., 2015). Other methods of data analysis were considered (such as framework analysis) but these would not have enabled adequate exploration of the feasibility of this novel treatment approach in a complex clinical setting, which demanded an unrestrained and exploratory approach.

Qualitative transcripts were read several times to familiarise myself with the data. An initial thematic framework was developed, based upon the early transcripts

and field diary entries, following which data were assigned to the themes drawn out from the transcripts. During analysis the themes, relationship between themes and interpretation were discussed with my supervisory team. In addition to the interview data, contextual information to assist the analysis was obtained from the free text box in the patient's case records on the Trust's electronic patient records system (PARIS). Rather than being used to corroborate participants' accounts, this information was used as 'stimulus material' (Barber, 2014) to situate participant's narratives within the context of therapy delivery by providing information about the number of sessions delivered and staff perspectives on those sessions. Again, this reflects the acknowledgement of the importance of context in the analysis, as well as content. It also allowed identification of the staff assigned to each participant, in order to establish links between staff and patient narratives. As in Stage I of this thesis, Figures have been used to create a visual to aid in illustrating the results.

The following section moves on to discuss the recruitment results.

Stage II Recruitment Results

Presentation of the results

As this is a mixed methods trial, the qualitative and quantitative data relating to the study recruitment will be presented together under relevant sub-headings (Cresswell, 2009). Where necessary, recruitment approaches begin with a descriptive prelude. This is followed by relevant qualitative findings, and then any related quantitative results. Each section ends with an integrated summary. The success of the study design and randomisation are then detailed. Direct quotes have been included where relevant, to enable the reader to judge the quality of research and claims made (Mason, 2002).

Patient recruitment

Recruitment was initially projected to last one year; in practice, it took place over a 17-month period; from March 2015 to July 2016. Trial recruitment was stopped at the end of the defined recruitment period: any potential participants who had not progressed to entering the study by July 2016 were not included (i.e., those on internal service waiting lists). The study formally ended seven and a half months following the date the final participant was randomised into the study (March 2017).

Flow of patients through the trial

A total of 351 young people were screened for inclusion in the BUDDY study from three CAMHS. Patients were referred to the study via three different recruitment methods; a researcher case note review, by clinicians during routine appointments or a poster displayed in CAMHS waiting rooms enabling patients or their families to

refer themselves into the study. Two hundred and sixty seven young people were screened in the case note review (eight of which were deemed provisionally eligible), four families contacted the study team after seeing the study poster (three of which were provisionally eligible) and 80 were approached by their CAMHS clinician (53 were provisionally eligible). Following screening 287 patients were excluded, leaving 64 who met the provisional eligibility criteria; a rate of 18%. Those identified as provisionally eligible were invited to attend a diagnostic interview. Following this invitation, a further 38 were excluded prior to the diagnostic interview due to no longer meeting the inclusion criteria (n= 1), being discharged from the service (n= 15), transferred to a Tier not participating in the study (n= 3), declining participation (n= 10) or being withdrawn by their clinician (n= 9). Twenty-six were subsequently assessed for eligibility using the K-SADS-PL diagnostic interview. Twenty five (96%) were identified as having MDD and met the study inclusion criteria (prior to randomisation, one of these patients was excluded by the clinical team due to the severity of their condition, two further patients remained on an internal waiting list and were not allocated to a clinician within the timeframe of the study), leading to 22 patients being randomised into the trial (see CONSORT diagram in Figure 7). From the pool of original patients screened and referred to the study, those randomised represented an inclusion rate of 6.3%. Eleven participants (50%) were allocated to BA and 11 (50%) to TAU. In the BA arm, one participant was excluded from the study post-randomisation by their CAMHS clinician and was not offered BA treatment (or invited to follow-up assessments) and another did not respond to a letter from the service so was discharged prior to treatment. In the TAU arm, two patients were also discharged prior to receiving any treatment. Primary outcome data (K-SADS-PL MDD

diagnosis at three-month follow-up) were available for 15 patients (68%), representing a loss to follow-up of 32% (36% in BA group and 27% in the TAU group). Two of those randomised to BA treatment did not attend and one other declined to attend the three and six-month follow-up sessions. Two others did not attend the six-month follow-up appointment. In the TAU arm, one participant did not attend follow-up at three or six months and two others did not attend three-month follow-up but did complete six-month follow-up. At six-month follow up, 11 patients were retained (including the two participants who did not provide three-month follow-up data), with a loss to follow up of 50% at six-months (55% in BA group and 45% in the TAU group). Further details relating to the exclusion of potential participants at each stage will be detailed below.

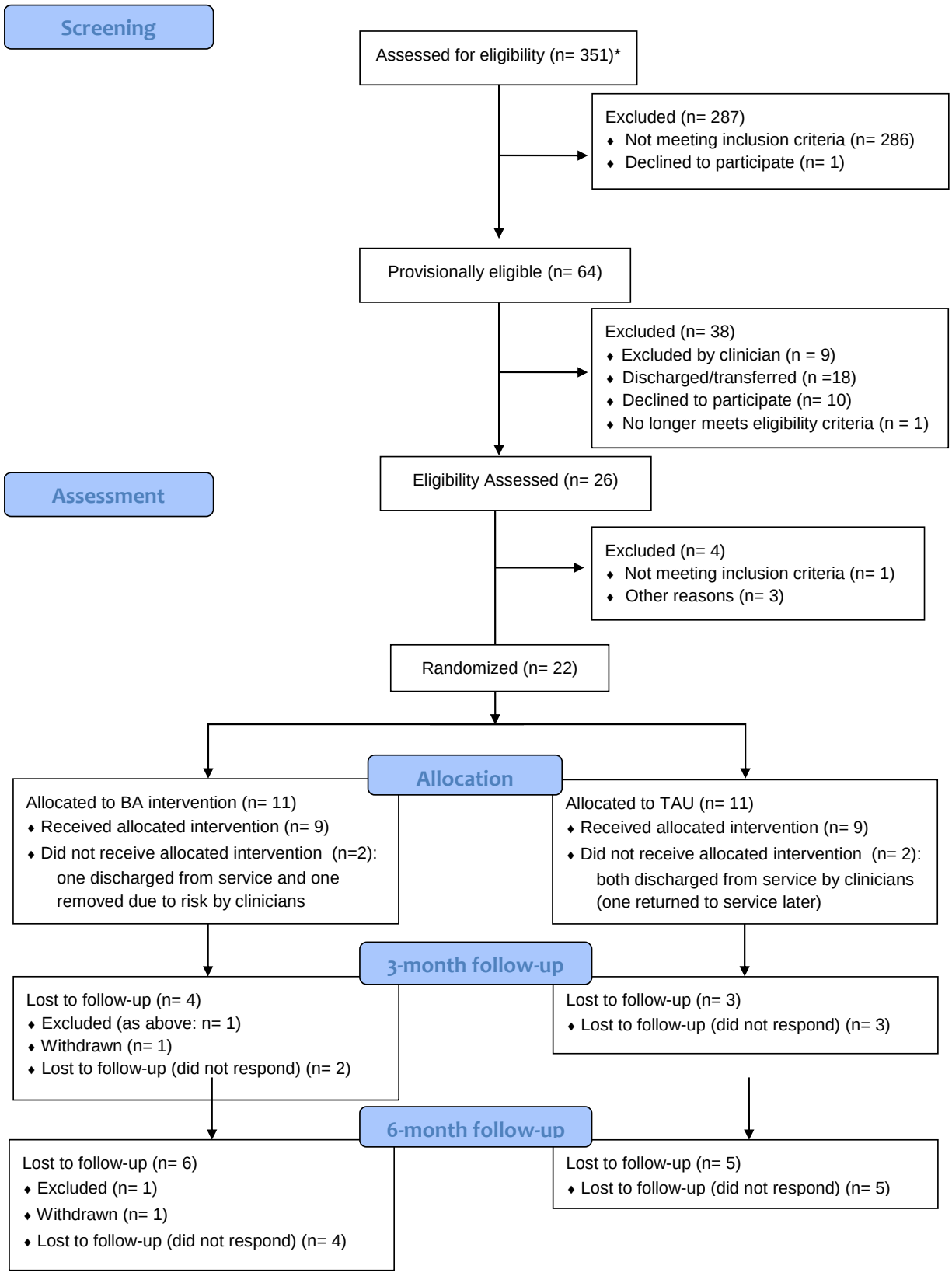


Figure 7: CONSORT Diagram: flow of participants through the BUDDY study.
***Identified by case note review (n= 267), study poster (n= 4) or clinician (n =80)**

In Table 8, participants assigned to BA treatment have been allocated a pseudonym to preserve anonymity, assist in differentiating between participants and to aid interpretation of the findings. Six of those young people assigned to BA treatment and five of their parents attended a qualitative follow-up interview once treatment was complete (indicated in bold in Table 8). When participating young people were asked if they would like their parents to be present during their interview all but one invited their parents to attend (n= 5); this one young person opted to attend alone due to their parents' lack of availability. In Table 9, all clinicians trained in the BA intervention (those that progressed to participate in the study) have also been assigned pseudonyms; five of the participating staff were interviewed (indicated in bold). One member of staff declined the offer of an interview, due to a lack of time. In all combinations of therapist/young person, either the member of staff delivering the therapy or the young person receiving it were able to be interviewed. In order to assist with identifying which quotes are from a staff or a participant pseudonym; staff have been assigned an identification number preceded by an 'S' and participants a number starting with 'P'.

Table 8: Participant pseudonyms and characteristics; bold font indicates those who attended the qualitative interview

Pseudonym	Identifier	Number of BA Sessions	Gender	Age	Tier
Jennifer*	P1	2	f	14	3
Frankie*	P2	3	f	17	3
David	P3	8	m	17	3
Jessica***	P4	0	f	17	2
Estelle	P5	8	f	14	2
Lucy	P6	8	f	13	2
Sophie***	P7	0	f	16	2
Victoria*	P8	7	f	14	2
Connor*	P9	4	m	14	2

Neive*	P10	3	f	15	2
Alicia	P11	8	f	17	3

Participants where: *treatment incomplete *** treatment not started

Table 9: Staff pseudonyms and characteristics; bold font indicates those who attended the qualitative interview

Pseudonym	Identifier	Number of BA patients	Gender	Age	Tier
Geoff	S1	3 (2*)	m	-	2
Nicola	S2	2 (1**)	f	-	2
Shane	S3	1	m	-	3
Paul	S4	2 (1***)	m	-	2
Sharon	S5	2 (1*)	f	-	3
Bridget	S6	1*	f	-	3

Number of the clinician's patients where: *treatment was incomplete **excluded by researchers from the study *** treatment not started

As detailed in the methods section, three different methods for recruiting patients into the study were used and evaluated to assess their suitability for recruiting participants into this feasibility trial: a case note review of patient electronic records, a poster displayed in the site waiting rooms asking patients to identify themselves as suitable for the study and identification of patients by clinicians during routine appointments. Patients were deemed provisionally eligible if aged between 12 and 17 years old, were not under the care of the LD team or had a LD that may have made it difficult for them to engage in the intervention, had not started psychotherapy and depression symptomology had been noted in their records.

Recruitment approach

Case note review

A case note review was conducted at two of the three study sites; Site One and Site Three. The case note review at Site Two was unable to be effected due to a lack of resource. Both initiated reviews covered only a sub-section of the available case notes, due to a lack of time to complete the full reviews as intended. The main

reason for this was the lack of functionality in the Trust patient records system (PARIS) which made it impossible to refine patient searches, meaning that each case note had to be reviewed individually, rendering the process extremely labour-intensive. Although aware of many of these difficulties prior to the start of the study (from Stage I of the research), there were additional unanticipated factors that compounded these problems when using this method of patient screening. When an individual patient record was accessed, it had to be manually cross-checked against the study recruitment spreadsheet (of those case notes already reviewed) in order to check for duplication. Duplication was particularly problematic when screening case notes in this way; for example, one patient may have had an assessment in Tier 2, progressed to Tier 3 for a more specialist assessment and then been allocated to a 'lead professional' who required a cognitive assessment to be completed by a 'co-worker'. This would lead to the young person being on the caseloads of four staff members. In some cases, once the clinician's work with the young person had been completed, the patient may have been removed from the staff's caseload but this occurred on an ad hoc basis. As such, each staff member had large numbers of patients on their caseloads and some patients were therefore reviewed multiple times, leading the case note review to be inefficient. Another difficulty was the order and number of patients on a staff's caseload changed on a daily or weekly basis (i.e. when new patients were added or removed), which made it difficult to crosscheck against the recruitment spreadsheet. Additionally, once a patient ID had been cross-checked against the spreadsheet for duplication, several different screens had to be accessed to obtain the required information. If the young person was excluded due to being outside the required age range, this information could be found easily

within a few seconds as it was on the PARIS patient header; however, assessing if the patient had an LD (but not one severe enough to enable them to be treated by the LD team), depressive symptoms or had received psychotherapy was much more challenging and often involved reading through tens of individual clinical entries which could take up to 20 minutes per patient case note. Due to the difficulties described and the success of the other two methods of recruitment, there was less reliance upon this method of participant recruitment and, relatively early on in the recruitment period, clinician identification was prioritised over case note review tasks.

In contrast to the difficulties experienced implementing this method of case finding, during the qualitative interviews when CAMHS clinicians were asked about how families were identified to take part in the study, Shane (S3) felt a case note review must have been a helpful method, yielding many potential participants. During the participant and carer interviews there were no comments relating to this approach method, which is not surprising as none of the families taking part in the interviews were ultimately recruited in this way.

At Site One, 178 electronic patient records were screened for provisional eligibility for the study, yielding one provisionally eligible patient. One further patient was provisionally eligible but had previously been approached by their clinician where they declined the invitation to participate (so was considered not to be provisionally eligible). At Site Three, the electronic patient records of 89 young people were screened, yielding eight young people who were provisionally eligible (84 of these case notes were reviewed by an Assistant Psychologist to facilitate

identification of potential participants). See Table 10 for further details of the profiles of the patients screened using this method.

Table 10: Patient characteristics of those screened in the case note review

	Site One	Site Three
No. screened	178	89
Male	148	52
Female	30	36
Unknown Gender	0	1
Median Age	11	10
Excluded for Age	96	57
Excluded for LD	7	0
Excluded already receiving treatment	24	15
Excluded no depressive symptomology	48	9
Excluded previously been approached	1	0
Excluded duplicate	1	0
No. provisionally eligible	1	8

Of the 267 patients screened using this method, only 9 (3.4%) were provisionally eligible. One of these had to be subsequently excluded as, between the point when they were identified via the case note review and when they were contacted to participate in the study, they had started group therapy for their depressive symptoms. Eight participants (3% of those screened using this method) therefore went forward as provisionally eligible.

Poster recruitment

Three members of staff participating in the qualitative interviews commented specifically on the presence of the poster in their CAMHS waiting room, which they felt was of good quality and a helpful way to approach participants. When young people were interviewed, Jennifer (P1) and her carer described how they were recruited to participate in the BUDDY study after viewing the poster that was

displayed in the waiting room of the CAMHS they were attending and they were happy with this approach. They noted that their main motivation to participate was that they felt taking part in the study might ensure that they were given treatment after a long wait in the service already.

Four young people (all female, median age 14) were recruited directly using the poster. It is unknown how many patients viewed this poster. These four young people or their parents used the email or telephone number displayed on the poster/contact card to alert the research team directly. Of the four patients recruited using this method, three (75%) were provisionally eligible. When eligibility was checked for one patient, they had already started receiving psychotherapy so had to be excluded. A further four young people were prompted by the poster to approach their clinician about the study. The clinician then approached the research team on their behalf so they are reported under the clinician approach figures.

Clinician recruitment

Clinician recruitment took two forms; referral by the clinician to the research team (where the researcher invited the participant to hear more about the study by letter) or direct approach by the clinician. One parent (who had seen the study poster and expressed an interest in the study to their clinician) reported that their poor literacy had led to difficulties reading the study information provided. Although this problem was able to be resolved at their next appointment with their clinician who went through the information with the family. During the qualitative interviews, all five participating young people (and four carers) reported that they were happy with being approached by their clinician and could not identify a more preferable way to be asked to participate. Lucy (P6) said “I think it was good the way they [the clinician]

dealt with it, how they put it across". Jessica (P4) also felt "quite positive about it [the clinician recruitment process] because I didn't feel like it was forced on me in any way, and I felt like I was welcome to talk about anything that I wanted, or leave anything". Estelle's parent (P5) reported the recruitment process happened quickly. This was in contrast to the long wait for the service, which they were dissatisfied with and had complained about prior to entering the study. Similarly, Lucy had an expectation that taking part in the study would lead to receiving care quicker than usual. When young people were asked to consider alternative approaches, David (P3) felt a letter (as he received from the research team following the initial clinician approach) would be preferable to being approached via a telephone call.

When staff were interviewed, they reported being pleased with their role in recruiting potential participants during their routine consultations, feeling that it worked well for them and the families they were approaching, as well as it appearing to be a successful way to recruit patients into the study. Although Geoff (S1) felt that "it took a little while to get it into your mind-set", once he had taken on this recruitment role he felt it led to the successful recruitment of a significant number of potential participants. This reference to requiring time to absorb the recruitment criteria appears to echo one of the earlier findings in Stage I, relating to the concept of staff 'headspace' and the importance of this in order to participate in research (see Chapter 3). Shane (S3) highlighted the benefits of the researcher being available to support staff in their role of identifying potential participants; "a lot of people, even though the criteria for their entry into the study were made quite explicit, wouldn't understand [the study entry criteria], both service users and staff". Shane described the availability of a researcher onsite as an important control to stop the

recruitment of unsuitable applicants due to the misinterpretation of recruitment criteria by inexperienced staff. This can again be linked back to staff confidence, which was illustrated ethnographically in Chapter 3. Paul (S4) discussed how Tier 2 staff were particularly well suited to undertaking a recruitment role due to the numbers of patients that they see and that they often undertook initial assessments when young people were referred to the service, suggesting that "it seemed to be an opportune time to pick them up". In contrast, Geoff felt that Tier 2 staff were restricted due to their assessment sessions being too short to obtain the information required to make a decision about young people's suitability for the BUDDY study. One member of staff, Sharon (S5) thought a more efficient strategy would be to attend staff referral meetings, although she implied these were not currently taking place in her team. Nicola (S2) proposed that to increase accessibility to the study young people could be recruited from outside of CAMHS by drawing a wider net to include schools, possibly via school councillors. Shane (S3) felt GPs may be in the best position to provide referrals into the study. In a broader sense, he discussed the importance of approaching the right staff to participate in the project, rather than just focusing on recruiting the right patients.

> "I think the key to getting people involved and getting the right people involved isn't about how you approach the families, it's about how you approach the staff. And I think if more staff who are doing initial assessments, if the primary mental health teams who are doing access to service appointments, maybe even GPs who have this information available, assuming they'd be able to [refer] straight in… Have the information of this is what makes a person suitable, then I think if they had that information and understood it and remembered it, that's how you'd get the best influx I think" [Shane S3]

The amount and depth of feedback received from staff, demonstrated the level of investment in the BUDDY study and provided insight into plausible alternative ways to approach young people to participate in future studies.

In addition to the four young people who were recruited by their clinician through the study poster, a further 76 young people were recruited directly by their clinician (see Table 11). Of the 80 patients referred via this method, 53 (66.3%) were provisionally eligible. The majority of those deemed provisionally eligible were recruited by Tier 2 staff. See Table 11 for a breakdown of the reasons the 27 were excluded; of those instances where the patient was already receiving treatment (n= 5); three were receiving Cognitive Behavioural Therapy (CBT), one Dialectical Behaviour Therapy (DBT) and one an unspecified treatment. In three cases, patients no longer met the criteria for low mood; the depressive episode had resolved for one of these patients (as assessed by a Psychiatrist) and in the other two cases, although the initial referral to the service indicated low mood, this was not found when the patient was assessed by a clinician. Where clinicians withdrew participants (n= 2), one clinician wished to keep patient for a case study in their CYP IAPT training course and another expressed concern that the patient had ulterior motives for attending CAMHS so would be unsuitable to participate. Where patients declined participation (n= 3) this was due to families returning the consent-to-contact form indicating they did not want to receive further details relating to the study. Two young people were referred outside of the study recruitment window so their eligibility was not assessed. Notifications in error (n= 2) were due to clinicians selecting the incorrect alert function on PARIS where they alerted the whole CAMHS team to the case rather than the intended clinicians.

Table 11: Patient characteristics of those referred into the study via clinicians

	Site One	Site Two	Site Three
No. referred	47	28	5
Male	12	8	0
Female	35	18	5
Unknown Gender	0	2	0
Median Age	15	16	15
Excluded for Age	1	0	0
Excluded for LD	1	0	0
Excluded already receiving treatment	5	0	0
Excluded no depressive symptomology	3	0	0
Excluded withdrawn by clinician	2	0	0
Excluded patient declined	3	0	0
Excluded urgent care required	2	4	0
Excluded outside recruitment window	1	0	1
Excluded notification in error	1	1	0
Excluded duplicate	0	2	0
No. provisionally eligible	28	21	4

Patient recruitment summary

All three recruitment strategies appeared to be well received by patients, their parents/carers and clinicians, with no negative comments on the methods of recruitment trialled. However, the case note review was not found to be feasible from a researcher perspective. The poster content and presentation appeared to be satisfactory to staff and patients recruited via this method. Clinician approach was acceptable to patients and valued by staff, despite initial reservations. There was a lack of consensus on which Tier would be best placed to recruit participants into the study. Despite one member of staff raising concerns that assessment sessions may be too short within Tier 2, clinicians were found to be accurate at identifying provisionally eligible young people and the majority of provisionally eligible participants were recruited from Tier 2.

We were interested in exploring which of the three recruitment methods yielded the greatest number of provisionally eligible patients. Figure 8 (i) illustrates the proportion of patients subsequently deemed provisionally eligible recruited using each different method or combination of approaches. Clinician-led approaches were responsible for recruiting the greatest number of provisionally eligible patients; 82.8% of participants were recruited by clinicians compared to 4.7% who were self-identified and 12.5% who were identified by researchers. However, the results also suggest that self-selection (via the poster) was an effective approach; with 75% of those identified using this method being provisionally eligible compared to 66.3% for clinician-led and 3% for research-led approaches (see Figure 8 [ii]).

i) ii)

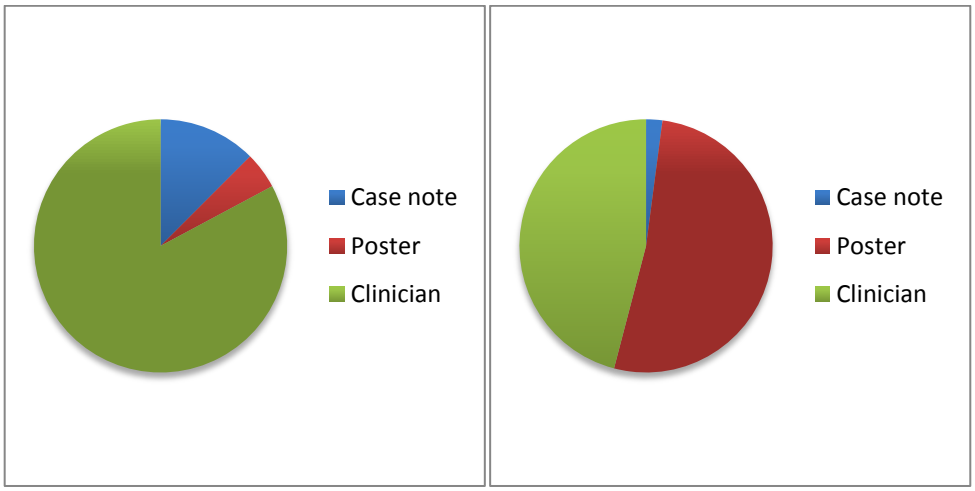


Figure 8: Pie-chart illustrating i) the numbers of provisionally eligible patients derived from each different recruitment method ii) the proportion of those identified from the total number screened using each recruitment method

Participant Eligibility

Those deemed to be provisionally eligible (n = 64) were invited to an information session and subsequent diagnostic interview. Thirty-eight of these provisionally eligible participants were excluded prior to being able to attend an information

session. One of these also no longer met the provisional inclusion criteria. Fifteen had been discharged from CAMHS care (patients dropping out/withdrawing from the service or staff discharge due to improvements in depressive symptomology, the availability of alternate service provision or no response from families to letters from the service) and a further three patients had been transferred to Tier 3 of Site Three where no clinicians were able to be trained in BA so had to be excluded. Ten of those invited, declined after receiving the study materials (one of these was after attending the information session); one stated they did not like the weekly format of BA (and wanted to receive treatment on a monthly basis), one did not want to risk being allocated to another clinician after meeting their current clinician (i.e. during randomisation), one did not like talking therapies, five did not provide a reason and two did not attend the information session. Nine were excluded by their clinician; one clinician was not happy for the research team to approach the patient, three thought the case was too complex or BA was too simple, one wanted to use the patient as a case study for their CYP IAPT training course, one felt another comorbidity needed to be prioritised, one patient required urgent treatment and two clinicians felt a group therapy approached was needed. Therefore, 26 patients progressed to assessment in the K-SADS-PL diagnostic interview. One young person did not meet the criteria for MDD during the K-SADS-PL assessment, leaving 25 young people who met the study inclusion criteria. Following the diagnostic interview, the CAMHS team withdrew one participant due to the disclosure of additional risk during the K-SADS-PL; this occurred prior to randomisation. Two further patients remained on an internal waiting list and were not allocated to a clinician within the timeframe of the study. These patients could not be included in

the study because they would not have been able to be randomised due to the stratification in the randomisation list requiring knowledge of which Tier their allocated clinician worked in. This lead to 22 patients being randomised into the trial.

Qualitative feedback on treatment allocation

Young person and caregiver views on the treatment options offered

An important part of any psychotherapy trial, particularly at the feasibility stage, is to understand how young people and their parents/carers might view the different treatment options offered to them. In this study, families were offered either BA or TAU (described as 'Combined Treatment' in the study materials). This was explored with those allocated to BA treatment during the qualitative interviews and across both treatment groups in the end of treatment survey at the three-month follow-up. One parent felt the researcher had expressed a preference in favour of BA "because if I remember rightly you talked to us about it and this one was the best one", so the patient was pleased with their allocation to BA. This impression was most likely gained from the treatment description because the same parent also noted "…this is all new to us" when asked if they had any prior expectations of the type of treatments that would be offered to them. However, their young person Estelle (P5) stated:

> "I didn't know anything about the other option, so I didn't have a favourite because I didn't know about them. So that was fine"

No young people or other parents expressed a preference for either treatment option. As indicated by Estelle above, it was common for participants and their families to not have an in depth knowledge about either of the treatment options available. In fact, Jennifer (P1) reported that she was not aware that the two treatment options were different to one another and Frankie (P2) and their parent

suggested they may have forgotten about what each treatment consisted of but were happy with the one they were allocated. Two other young people clearly stated that they did not prefer one treatment over the other, with David (P3) saying "I didn't really mind. I didn't really care which one I went on". He went on to explain that he didn't have any pre-conceived expectations prior to treatment of what type of care to expect. This was seconded by Jessica (P4) who stated:

> "I didn't really mind which one I got. I was happy to talk to anyone about it at that point, I think, because I was, I don't know, I didn't really know what would do what differently so yeah I didn't mind at all"

Jessica had been offered CBT in the past, which had shaped her expectations of treatment. Although a cognitive approach had been helpful to her, she remained open minded to other treatment options: "I didn't really know much about the others because it was just what I had been offered. So I didn't really have a preference" and "I was quite open to it and what it involved". Frankie's parent reiterated the sentiments of their young person above, saying:

> "We just thought we'd give it a go, love, didn't we? And we went with a bit of an open mind and decided to do one session and see how it went. I think [Frankie] was just happy to go along with whatever was suggested"

Lucy (P6) stated "I wouldn't have minded either of them. I think they both seemed pretty good". Their parent then continued by saying "We didn't know anything about the process anyway because we've never been involved in anything like this. So it wouldn't have mattered, I don't think which one, which route we went down really". This lack of previous experience meant they had no prior knowledge on which to base any expectations of the type of treatment they would be offered. There is a clear message from this feedback that families did not have a preference for any particular treatment approach, they were open-minded to different care options and

most were naïve to the treatments offered routinely by the service. Worryingly, most families did not appear to have fully understood the different treatment options offered in the study. It may be that they had not retained this information several months after being presented with it or that they had not understood it at the time. This may be linked to the faith that families invested in the service or in the researcher, trusting in them to provide appropriate care.

Only one member of a participating family (a parent of Jennifer P1) expressed any alternative treatment preference to those that were offered. This carer would have liked to have been offered hypnotherapy as a treatment option because it would mean "they [the CAMHS team] could have changed the way [Jennifer] thought without [her] having to put in any effort". Such expressions should perhaps alert us to whether, and if so, how families' prior expectations of treatment might influence subsequent engagement in their care. In this case, for instance, the parent did not want their young person to be an active participant in their treatment although this was only the case for one family.

Fifteen young people and ten parents completed the survey at the end of their treatment; seven (64%) of those who had been randomised to receive BA treatment (and four of their parents) and eight (73%) who had been randomised to receive TAU (and six of their parents). When asked whether they would have preferred the other option of treatment to the one they received; 57% (4/7) of those allocated to BA said they would not have preferred treatment as usual and 43% (3/7) didn't mind which treatment they were allocated to. This is in contrast to the findings in the qualitative interviews reported above, where most participants reported no treatment preference. Of those allocated to TAU, 12.5% (1/8) would not

have preferred BA treatment, 12.5 % (1/8) would have preferred BA treatment and 75% (6/8) didn't mind.

Staff reflections on allocation of patients to treatment

Although staff were not specifically asked about the treatment options offered, some staff members chose to provide feedback on the way patients were allocated to treatment or the treatment content within the study. Shane (S3) identified that, from a systems perspective, the randomisation process - particularly the stratification of staff by Tier (Tier 2 and Tier 3) - led to uneven numbers of young people being recruited within each Tier of each CAMHS service (at each site).

> "The allocation of service users to staff based on assessed risk and based on CAMHS service structure. So service users are predominantly initially seen by primary mental health workers and formally Tier 2, and those primary mental health workers would then if the risk was severe enough refer on to specialist CAMHS Tier 3. Because of the nature of your allocation system, we were finding that Tier 3 weren't seeing many people who were suitable for this study, because they'd either had prior intervention or the risk was so high there were very staff that they were able to be allocated to because of I suppose the limited training budget involved and the time demands on more experienced staff. Which meant from what I gather there was a huge influx of people suitable for Tier 2 services for PMHWs, but not suitable for CAMHS Tier 3 services" [Shane, S3]

The statement above is evidence of the enthusiasm and investment staff made to participate in the study and the disappointment expressed by this staff member that more eligible young people had not progressed into the study in the Tier that they worked in (Tier 3). This staff member had an in-depth understanding of the study design and offered his views on how this could be improved. He observed that Tier 3 were seeing fewer eligible patients as many of the Tier 3 patients were excluded from the study due to prior intervention in Tier 2 or their risk level being too high (i.e. requiring urgent care). This meant that they did not meet the study entry

criteria, which would have implications for a larger trial where these issues would become magnified. In the context of this study it meant there was more demand on staff trained in Tier 2 than those in Tier 3, which placed an uneven burden on those participating and offered less of an opportunity for Tier 3 staff to practice and utilise the skills learnt in the BA training.

Stage II Quantitative Results

Presentation of the results

The results in the following section are mainly quantitative but qualitative data have been added where relevant to reduce repetition in the qualitative results section that follows and to provide context to the quantitative results. As in the recruitment results above, participant and staff pseudonyms have been used for the qualitative data (see Table 8 for participant pseudonyms illustrated with a 'P' and staff pseudonyms in Table 9 illustrated with a 'S').

Data quality

In any study, whether the approach is qualitative or quantitative, there is the potential for errors to occur in a dataset when collecting, transcribing and entering data (Petrie and Sabin, 2009). Errors can lead to misinterpretation of the study results.

After completion of the data collection, the randomisation list was revealed. The statistician had employed a repeated block size of eight. At this point, an error was identified. The error was made by one of the University secretaries completing the remote telephone randomisation and occurred when they misallocated one participant to the incorrect study site (due to the two separate site randomisation lists). Although this participant received the intended treatment allocation, it meant some participants following this allocation were allocated to the incorrect treatment group. In addition, one practitioner allocated to provide treatment in the BA arm was instructed by their Team Manager to also provide CBT in the control arm due to

a lack of other CBT practitioners for one participant. This is important because it could be a source of treatment contamination.

To reduce the chance of errors, the quantitative data set were visually examined for outliers or errors and data were entered onto the spreadsheet and then cross-checked against the raw data (original questionnaires) prior to analysis. This was possible with such a small data set but in a larger trial other methods, such as double data entry (where data is entered twice and the two data sets are compared using a computer program) may be required to reduce the chance of errors. An error was identified due to the MFQ-C score being entered twice; once in the correct column and then in the MFQ-P column. This was identified on visual inspection as the young person was aged 17 so should not have had a parental questionnaire completed. Identified outliers were cross-checked with source records and found to be genuine scores.

Baseline diagnostic assessment

After providing consent to participate, young people proceeded to the diagnostic interview (K-SADS-PL [including CGAS]) and were asked to complete other measures (MFQ-C [and MFQ-P for parents RSE and BADS). Those deemed eligible were randomised following this assessment appointment; the characteristics of those randomised to participate in the trial are reported below.

Although young people were not specifically asked about the baseline assessments in their qualitative interviews, Jessica (P4) said “talking about everything on such a large scale in one session was helpful because it was uncovering everything at the same time…and after talking to you about everything it

was kind of easier to see the bigger picture". This provides some provisional indications that the baseline assessments were acceptable to participants.

The baseline characteristics at first research assessment prior to randomisation of all randomised participants can be seen in Table 12 (82% female; mean age 15 years and 7 months [1 year and 2 months SD]) which have been presented according to treatment group. Ethnicity data was unable to be collected from PARIS. Average depression score as measured by the MFQ-C at baseline was 34.73 points, over the threshold of 29 or more as a screen for depression. Average depression score as measured by the MFQ-P at baseline was 29.38 points, again over the threshold of 21 or more as a screen for depression. Average self-esteem score as measured by the RSE at baseline was 11.77 points was below 15, which is an indication of low self-esteem. Average CGAS score was 57.1 indicating variable functioning with sporadic difficulties or symptoms in several but not all social areas of the young person's life (as rated by the researcher). According to the BADS, participants varied in terms of their ability to complete tasks, the amount and type of self-reported activity they undertook (as well as whether they enjoyed those activities), avoidance and rumination. Most reported taking part in few activities over the past week, did not report making good decisions relating to the type of activities or situations they put themselves in and tended not to consider themselves active or having achieved the goals they had set themselves. The number of comorbidities that participants met the screening threshold for according to the K-SADS-PL was high, demonstrating the complexity of the patients treated as part of this study. All eligible participants met the screening threshold for co-morbid overanxious/generalized anxiety disorder.

Table 12: Baseline participant characteristics as randomised

Characteristics		BA (n= 11)	TAU (n= 11)
Sex, No. (%)	Female	9 (81.8)	9 (81.8)
	Male	2 (18.2)	2 (18.2)
Age at consent, y:m	Mean (SD)	15:8 (1:5)	15:5 (1:0)
	Median (range)	15:10 (13:11-17:7)	15:7 (13:8-16:10)
K-SADS-PL, No. (%)	No. (%) with data	11 (100)	11 (100)
Diagnosis*	MDD	11 (100)	11 (100)
	Melancholic	4 (36.4)	4 (36.4)
	Atypical	2 (18.2)	2 (18.2)
Severity	Mild	4 (36.4)	6 (54.5)
	Moderate	3 (27.3)	2 (18.2)
	Severe	4 (36.4)	3 (27.3)
Comorbidities*	No. (%)	11 (100)	11 (100)
	Mean (SD)	4.55 (1.21)	3.64 (1.75)
	Median (range)	5 (2-6)	4 (1-6)
	Mania	1 (9.1)	1 (9.1)
	Panic Disorder	4 (36.4)	4 (36.4)
	Separation Anxiety Disorder	6 (54.5)	3 (27.3)
	Avoidant Disorder/Social Phobia	6 (54.5)	5 (4.5)
	Agoraphobia & Specific Phobias	3 (27.3)	2 (18.2)
	Overanxious/Generalized Anxiety Disorder	11 (100)	11 (100)
	Anorexia Nervosa	1 (9.1)	1 (9.1)
	Bulimia Nervosa	1 (9.1)	0 (0)
	Attention Deficit Hyperactivity Disorder	4 (36.4)	1 (9.1)
	Oppositional Defiant Disorder	4 (36.4)	1 (9.1)
	Conduct Disorder	4 (36.4)	4 (36.4)
	Tic Disorders	1 (9.1)	1 (9.1)
	Post-Traumatic Stress Disorder	4 (36.4)	6 (54.5)
MFQ-C score[a]	No. (%) with data	11 (100)	11 (100)
	Mean (SD)	33.91 (11.8)	35.55 (11.09)
	Median (range)	34 (17-58)	35 (18-50)
MFQ-P score[b]	No. (%) with data	6 (100**)	7 (100**)
	Mean (SD)	29.83 (7.36)	29 (8.58)
	Median (range)	28 (23-42)	32 (16-38)
RSE score[c]	No. (%) with data	11 (100)	11 (100)
	Mean (SD)	11.09 (4.37)	12.45 (4.84)
	Median (range)	11 (5-20)	13 (6-21)
CGAS score[d]	No. (%) with data	11 (100)	11 (100)
	Mean (SD)	54.55 (9.47)	59.64 (6.8)
	Median (range)	58 (30-65)	59 (50-68)

BADS[e]	No. (%) with data	11 (100)	11 (100)

[a] Mood and Feelings Questionnaire: Long Version Child Self-Report (MFQ-C) score range, 0-66; higher scores indicate worse mood.
[b] Mood and Feelings Questionnaire: Long Version Parent Self-Report (MFQ-P) score range, 0-68; higher scores indicate worse mood.
[c] Rosenberg Self-Esteem Measure (RSE) score range, 0-30; scores between 15 and 25 are in the normal range, scores below 15 suggest low self-esteem.
[d] Children's Global Assessment Scale (CGAS) score range, 1-100; scores between 1-10 extremely impaired, 11-20 very severely impaired, 21-30 severe problems, 31-40 serious problems, 41-50 obvious problems, 51-60 some noticeable problems, 61-70 some problems, 71-80 doing alright, 81-90 doing well and 91-100 doing very well.
[e] Behavioral Activation for Depression Scale: Short Form (BADS) no score range as not validated in this population. Used only for descriptive purposes.
*Diagnostic categories/comorbidities are not mutually exclusive (i.e. one participant may meet the criteria for multiple depression-types/comorbidities)
**100% of those asked; only those young people aged 15 and under required parental consent to participate so only those parents were asked to complete the MFQ-P.

The continuous variables have been explored using the median and interquartile range to evaluate the impact of outliers across the psychometric scale scores and have been illustrated graphically to explore the distribution of scores. Each outcome measure will be discussed in turn.

Mood and Feelings Questionnaire- Child Version (MFQ-C)

The median MFQ-C score (n= 22) was 34.5 at baseline (range 17-58) and the interquartile range was 16.25 (26[Q1] - 42.5[Q3]). Prior to building a frequency distribution table, the number of class intervals in which to present the MFQ-C score data in a histogram were decided according to 'Sturges' Rule'. When applied to the MFQ-C data set, Sturges' Rule dictates the need to choose the smallest integer k such that $2k \geq n$ (see Table 13); as k= 5 was greater than our n value of 22, five intervals were selected. As well as the number of intervals, the size of each interval was decided using the maximum MFQ-C score of 58 and the minimum of 17 (range = 41). Each interval size is the difference in the maximum and minimum value divided by the number of intervals plus 1; giving an interval size of 9. Plots did not reveal a normal distribution on a histogram as the data set is not symmetrical (see Figure 9).

Table 13: Possible integers' for k

Integers for k
For k = 1, we have $2^1 = 2$
For k = 2, we have $2^2 = 4$
For k = 3, we have $2^3 = 8$
For k = 4, we have $2^4 = 16$
For k = 5, we have $2^5 = 32$

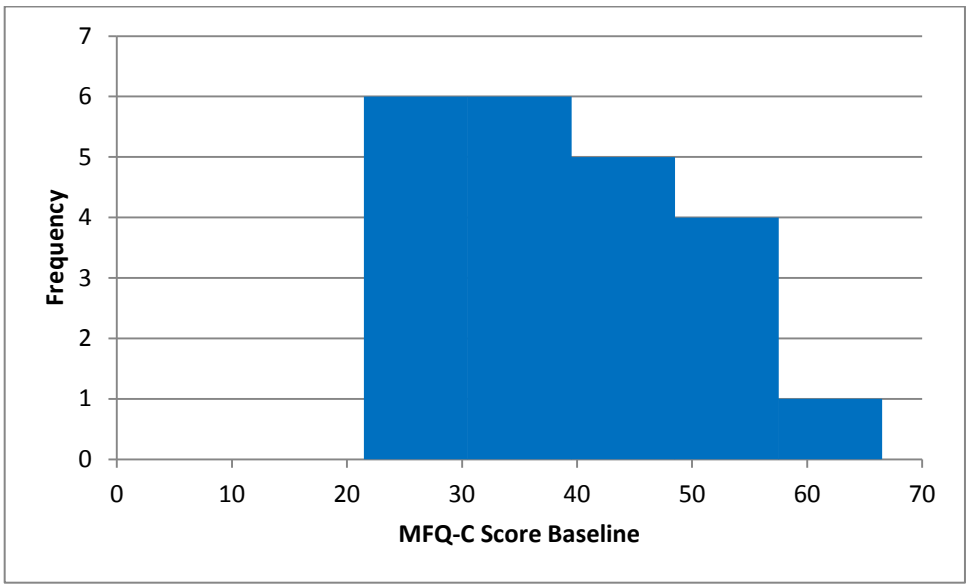


Figure 9: Histogram illustrating the frequency of MFQ-C scores at baseline

Mood and Feelings Questionnaire- Parent Version

The median MFQ-P score (n= 13) was 31 at baseline (range 16-42) and the interquartile range was 13 (23[Q1] - 36[Q3]). When applied to the MFQ-P data set, Sturges' Rule dictated the smallest integer (of k such that $2k \geq n$; see Table 13) was k= 4 which was greater than the n value of 13, so four intervals were selected. The interval size was decided using the maximum score of 42, the minimum of 16 and range of 26 (the difference in the maximum and minimum value divided by the number of intervals plus 1); giving an interval size of 7. Plots did not reveal a normal distribution on a histogram (see Figure 10).

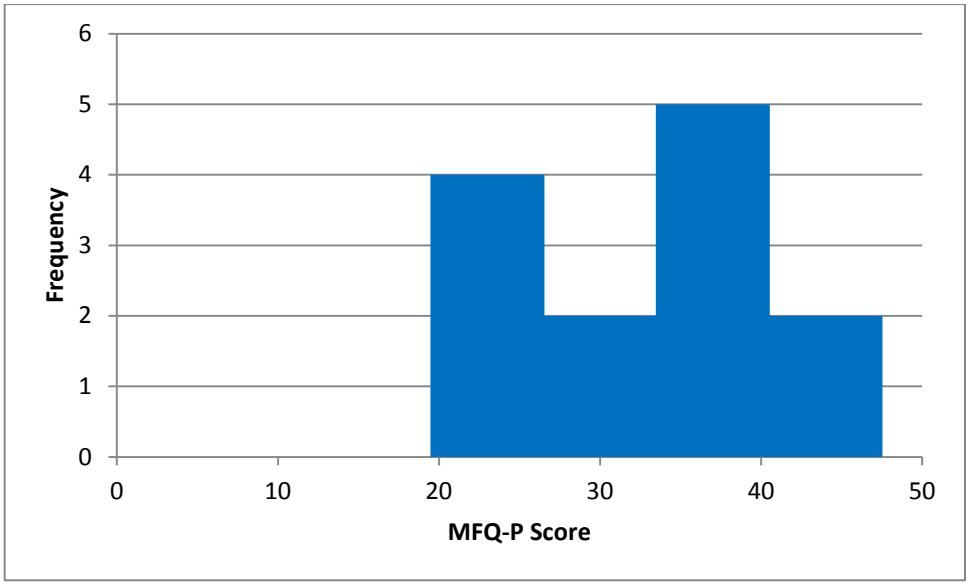


Figure 10: Histogram illustrating the frequency of MFQ-P scores at baseline

Rosenberg Self-Esteem (RSE)

The median RSE score (n= 22) was 11.5 at baseline (range 5-21) and the interquartile range was 6 (8[Q1] - 14[Q3]). When applied to the RSE data set, Sturges' Rule indicated k = 5 was greater than the n value of 22 (see Table 13), so five intervals were selected. The size of each interval was decided using the maximum score of 21, the minimum of 5 and range of 16. Each interval size is the difference in the maximum and minimum value divided by the number of intervals plus 1; giving an interval size of 4. Plots did not reveal a normal distribution on a histogram (see Figure 11).

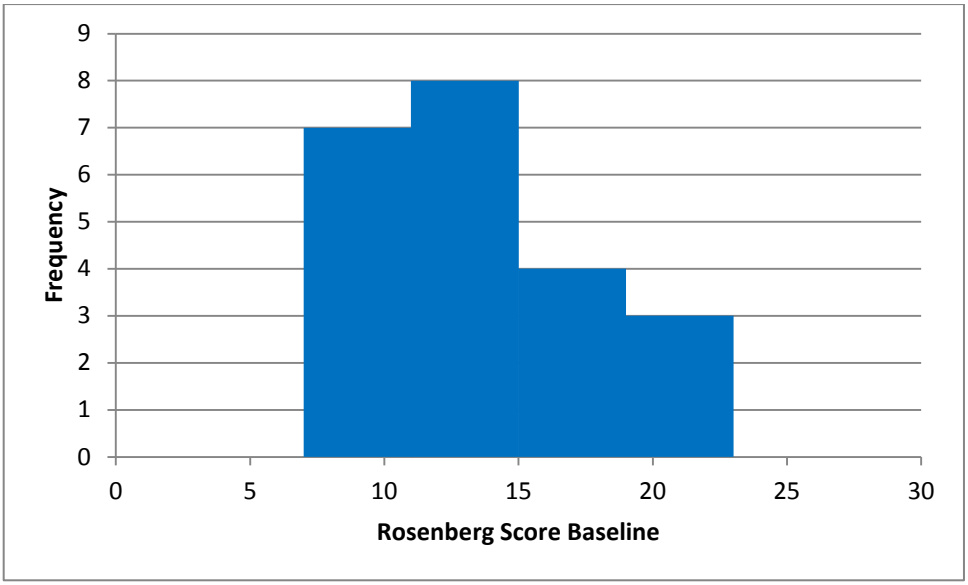


Figure 11: Histogram illustrating the frequency of RSE scores at baseline

Children's Global Assessment Scale (CGAS)

The median CGAS score (n= 22) was 58.5 at baseline (range 30-68) and the interquartile range was 5.75 (54.25[Q1] - 60[Q3]). When applied to the CGAS data set, Sturges' Rule indicated k= 5 was greater than the n value of 22 (see Table 13), so five intervals were selected. The size of each interval was decided using the maximum score of 68, the minimum of 30 and range of 38. Each interval size is the difference in the maximum and minimum value divided by the number of intervals plus 1; giving an interval size of 9. Plots did not reveal a normal distribution on a histogram (see Figure 12).

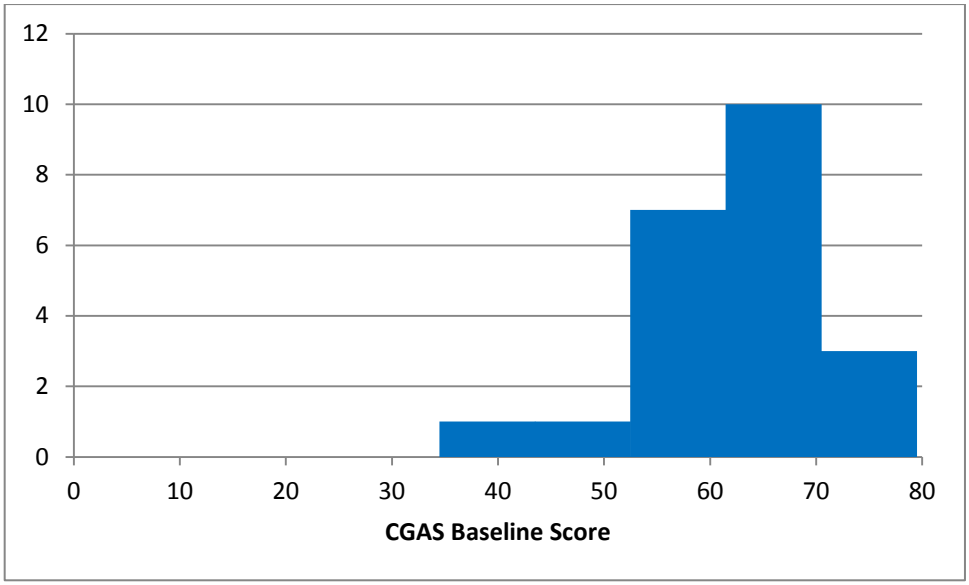


Figure 12: Histogram illustrating the frequency of CGAS scores at baseline

Treatment Group Differences

Randomisation should distribute known and unknown factors equally between the two groups, however due to the small sample size and the error in random allocation this was explored formally. Due to the small number of observations, with measures that followed a non-normal distribution any formal tests for inter-group differences were non-parametric in nature. Non-parametric tests offer a more conservative estimate of effect. A Kruskal-Wallis one-way analysis of variance was used to test for differences in baseline characteristics between treatment groups post-randomisation. There were two reasons for this; firstly, the size of each treatment group does not meet the sample size guidelines for the parametric alternative (ANOVA) of a minimum group size of 15 participants (Petrie and Sabin, 2009). Secondly, we cannot be confident that the data are normally distributed on the basis of Figures 9-12. In addition, there is no utility in using formal distribution tests (such as the Kolmogorov–Smirnov test) with such as small sample, as the test would lack the power to provide meaningful results.

No statistically significant differences were observed in scores at baseline between the two groups using a formal Kruskal-Wallis test on MFQ-C (BA mean = 33.91, SD = 11.8; TAU mean = 35.55, SD = 11.09; χ^2 for difference 0.24, p = 0.6), MFQ-P (BA mean = 29.83, SD = 7.36; TAU mean = 29, SD = 8.58; χ^2 for difference 0.05, p = 0.83), RSE (BA mean = 11.09, SD = 4.37; TAU mean = 12.45; SD = 4.84; χ^2 for difference 0.39, p = 0.5) or CGAS (BA mean = 54.55, SD = 9.47; TAU mean = 59.64, SD = 6.8; χ^2 for difference 1.10, p = 0.3). The two treatment groups were equal in size and comparable in patient characteristics at baseline.

Treatment delivery

Delivery of usual care

Clinicians in the BA arm were given specific instructions of the details to record on PARIS in relation to the delivery of the BA treatment (i.e., a brief description of the details of the manual that they covered during the session, any ROMs completed). There was an assumption that clinicians in the TAU arm would record their sessions in the same way, according to the guidance they had been issued through the CYP IAPT service improvement programme (noted in Stage I). This guidance emphasises the importance of accurate record keeping and the deployment of ROMs to monitor treatment outcomes. As it was, clinician record keeping in the TAU arm was generally of a very poor quality; although there was a great variation across teams and between individuals. As a result of the poor record keeping in relation to the occurrence and content of treatment sessions, it was extremely difficult to obtain even basic information from PARIS. Further to this, the process of obtaining the required information meant screening every entry of each patient's electronic

records for the study period, which could range from one or two to over one hundred entries across multiple pages per patient that had been entered by multiple clinicians. Many records were incomplete or contradictory. Appendix 14 provides an overview of the treatment pathways that young people who were randomised to TAU as part of the BUDDY study took through CAMHS.

Delivery of Behavioural activation

One clinician that received BA training left the service prior to treating patients in the study, another member of staff was unable to take on any BA patients during the study period due to taking on an additional management role. A further member of staff did not have any patients at their CAMHS site who were allocated to BA during the study period. Behavioural Activation was delivered by six clinicians (mean caseload of 1.8 randomised patients). Of the 11 patients allocated to BA, the nine participants who started treatment received on average 5.7 BA sessions (median, 7; range 2-8) over 4-13 weeks (median, 8). Of the two participants who did not start treatment, one patient was removed from the study (Sophie P7) by the clinical team and one was discharged (Jessica P4) from the service before treatment began. The average session duration was 49 minutes (range 30-80 minutes). Appendix 15 provides further details of the treatment pathways young people who were randomised to BA as part of the BUDDY study took through CAMHS.

Follow-up assessments

Response time

The average response time to assessments are detailed below in Table 14 from dates logged during the trial (although these do not account for non-working days, such as

bank holidays or weekends where it was not possible to complete assessments/post documents). The delay between receiving the referral and posting the materials reflects the difficulties accessing the electronic records system; as the researcher needed to be onsite to access participant personal details but had to be at the University to post the packs, this inevitably led to delays. Materials were posted second class so the delay from materials posted to first assessment reflects this and also the necessity of booking a room for the assessment to be held in, which frequently caused further delays. The delay from first assessment to randomisation was modest but could have been reduced if the remote randomisation service was available every day; however, due to relying upon people's good will this was not possible in this study. Both three and six month follow-ups on average were over three weeks late; this reflected difficulties booking rooms and also the fact that many young people missed or cancelled multiple appointments so they had to be rearranged at a later date.

Table 14: Response Time (days)

Average Time	Mean Days (including weekends and bank holidays)
Referral received to materials posted	19
Materials posted to first assessment	28
First assessment to randomisation	7
Date three-month assessment due to completion	21
Date six-month assessment due to completion	29

Impact of missing data

One reason one may complete an ITT analysis is due to concerns with the low rates of follow-up in the study, which may introduce bias if those participants who have dropped out differ in some respect to those who have attended follow-up

assessments. In order to investigate this, the baseline scores on the numerical variables were compared for those that did and those that did not drop out of the primary end-point at three-month follow-up.

There were no significant differences seen between those dropping out at three-month follow-up and those attending follow-up. Although those dropping out at three months appeared to have slightly higher baseline MFQ mood ratings on average, these were not found to be statistically significant for the MFQ-C (dropout mean = 37.14, SD = 14.79; no dropout mean = 33.6, SD = 9.51; $\chi^2 = 0.28$, p = 0.6), or MFQ-P scores (dropout mean = 31.8, SD = 5.12; no dropout mean = 27.88, SD = 8.97; $\chi^2 = 0.60$, p = 0.4). Average scores on the CGAS were almost identical in the two groups, also indicating no significant differences (dropout mean = 57, SD = 5.23; no dropout mean = 57.13, SD = 9.78; $\chi^2 = 0.28$, p = 0.6). In addition, although lower RSE scores (lower scores indicating lower self-esteem) can be seen in those dropping out (dropout mean = 9.86, SD = 4.38; no dropout mean = 12.67, SD = 4.5; $\chi^2 = 1.52$, p = 0.2) again this was non-significant. This indicates the remaining sample at three-month follow-up was broadly similar to those who entered the study.

Accounting for missing data

As a very large proportion of data was missing (particularly at six-month follow-up), if this was to be replicated in a larger trial it would represent a threat to the validity of the results. One significant concern when evaluating treatments for depression, is that the patients most severely ill may be the least likely to attend follow-up. If this was the case, it would be a source of bias because it is likely to give an overly optimistic view of the treatment by inflating the effect sizes of the treatment if the missing data is ignored. In this case, those remaining at three-month follow-up were

not found to differ significantly to those that entered the study at baseline in terms of depression symptoms, self-esteem and functioning. Despite this, it is important to explore the impact the missing data may have had on the results via a sensitivity analysis.

Descriptive statistics and exploratory statistical analyses

Complete baseline assessments (K-SADS-PL, MFQ-C, MFQ-P, CGAS, and RSE) were available for all participants. Of those that provided follow-up data at three and six months, only one questionnaire score was missing due to one parent not attending the session at three months (their young person attended alone). The quantitative results are summarised in Table 15 showing numerical data at baseline, three and six month follow-up for all participants randomised into the BUDDY study presented by treatment group.

Table 15: Comparison of groups for Outcome Measure Means (SD)

	Baseline		Three-month follow-up		Six-month follow-up	
	BA	TAU	BA	TAU	BA	TAU
MFQ-C	33.91 (11.80)	35.55 (11.09)	23.43 (9.59)	30.5 (8.67)	15.8 (6.22)	26.67 (12.6)
MFQ-P	29.83 (7.36)	29 (8.58)	29.33 (8.62)	26.6 (15.79)	11 (1.41)	27 (4.76)
RSE	11.09 (4.37)	12.45 (4.84)	14.57 (4.79)	13.5 (4.38)	15.8 (5.22)	14.5 (5.09)
CGAS	54.55 (9.47)	59.64 (6.80)	65.29 (14.03)	56.63 (7.82)	.	.

Depression diagnosis at follow-up (K-SADS-PL depression status)

The three-month follow-up represented the primary analysis point in this research and MDD status, as assessed by the K-SADS-PL, was the main outcome measure.

Depression status (MDD diagnosis or not) and depression severity (mild/moderate/severe) has been illustrated in Figures 13 and 14 according to the treatment group participants were assigned to at baseline and three-month follow-up. In Figure 13 and Table 16, there is a much larger reduction in those who meet the criteria for MDD on the K-SADS-PL in the BA treatment group compared to the TAU group, where a more modest reduction was observed. At baseline all participants were depressed (as per the study inclusion criteria), so a logistic regression was conducted to predict the odds of remission by treatment group at three-month follow-up. Due to the small number of observations, bootstrapping was used to sample (with replacement) over the distribution to derive the standard errors for the logistic regression models. In this case, the estimates of the standard errors stabilised after 3000 repeated bootstrapped samples. Those in the BA arm had nine times the odds of those in TAU to achieve remission, which was of borderline statistical significance ($\chi^2 = 3.35$, $p = 0.07$). However when this was re-ran without bootstrapped standard errors the effect of BA was significant at the $p<.05$ level (See Table 17). Therefore the analyses suggest that there was a trend towards those receiving BA treatment to achieve remission from depression.

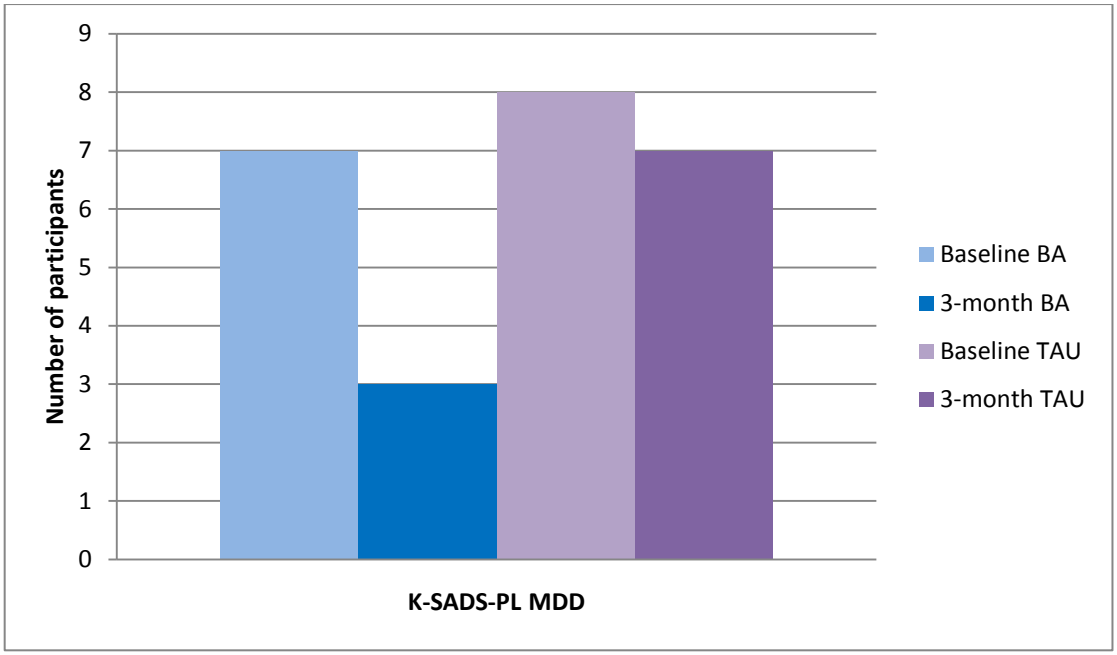


Figure 13: Baseline and three-month follow-up results (for those with available data) for a diagnosis of MDD on the K-SADS-PL

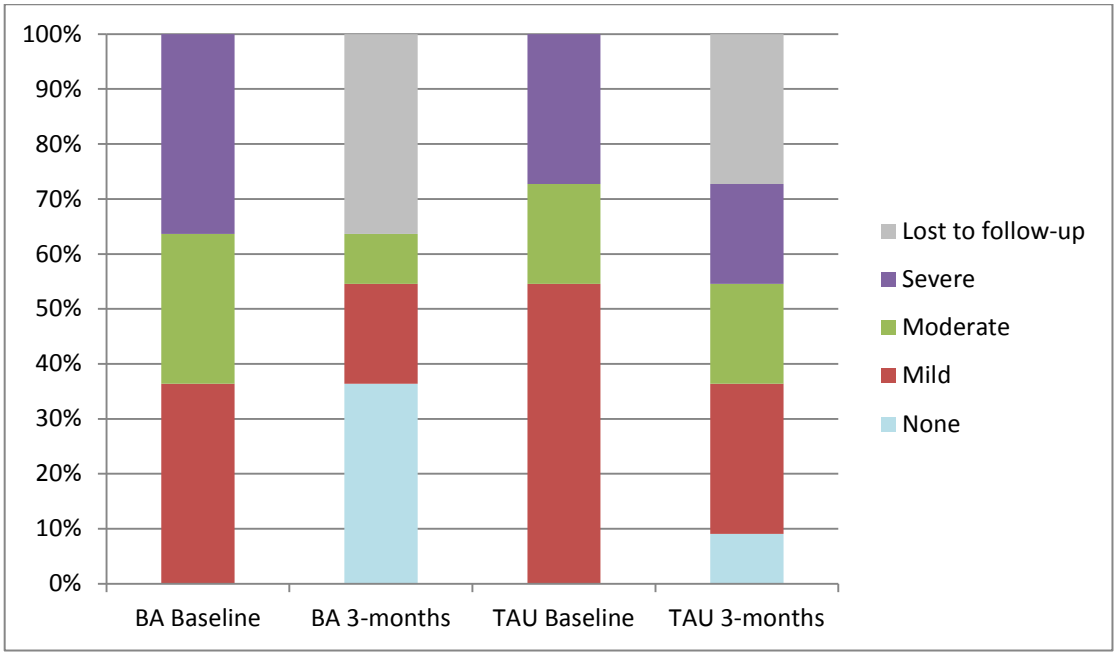


Figure 14: Severity level on the K-SADS-PL at baseline and three-month follow-up on the K-SDADS-PL. None represents non-MDD (so could indicate Depressive Disorder Not Otherwise Specified for example or no depression diagnosis at all)

Table 16: Showing the numbers of young people who achieved remission from depression according to treatment arm

Treatment	No remission from MDD	Remission from MDD	Total
TAU	7	1	8
BA	3	4	7
Total	10	5	15

Table 17: Results from a logistic regression analysis predicting remission from depression according to treatment group

	Observed Odds Ratio	Bootstrap Std. Err.	Z	P>|z|	95% Confidence Interval	
Treatment	9.33	8.85	2.35	0.02	1.45	59.92

As diagnosis of depression (MDD) is a dichotomous response (has depression/does not have depression), the responses on the K-SADS-PL depression interview were used to give a severity rating of the level of depression (mild/moderate/severe), to allow examination of any changes in depressive symptomology. In Figure 14, we observe that those who still meet the criteria for a diagnosis of MDD at three-month follow-up appear to be less severe in the BA arm (with a larger number experiencing mild or moderate depression) than the TAU (where there were a larger number with moderate and some participants who had severe depression).

Depression self-rated symptoms at follow-up (MFQ-C)

Figures 15 and 16 show a graphical representation of individual participant's MFQ-C scores at baseline, three and six-month follow-up (where follow-up data were available) in the BA and TAU arms respectively. At three-month follow-up, there was a downward trend in all scores for the BA participants except in one case where a strong increase in MFQ-C score can be seen between baseline and follow-up. At

three-month follow-up, the graph is flatter and more mixed for TAU participants with around half the scores increasing and the other half decreasing. Scores improved for both arms between randomisation and three-month follow-up, more so for the BA arm (from 33.91 at baseline to a score of 23.91 at three-months) than for the TAU arm (35.55 to 30.5).

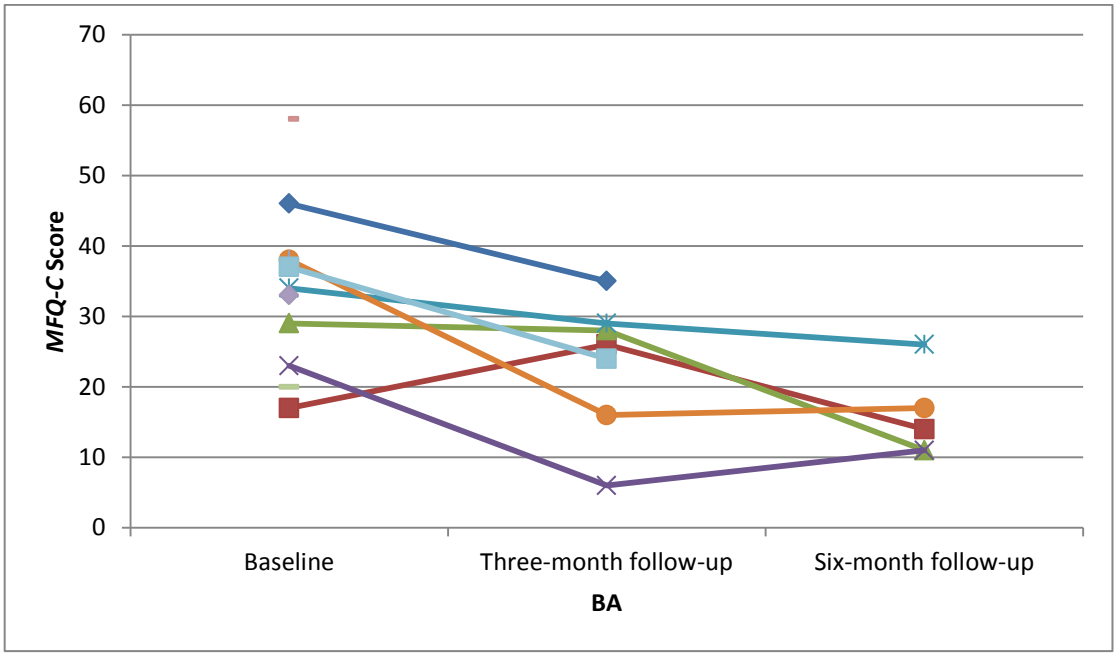


Figure 15: Participants in the BA arm, MFQ-C scores at baseline, three and six-month follow-up (for those who have follow-up data available)

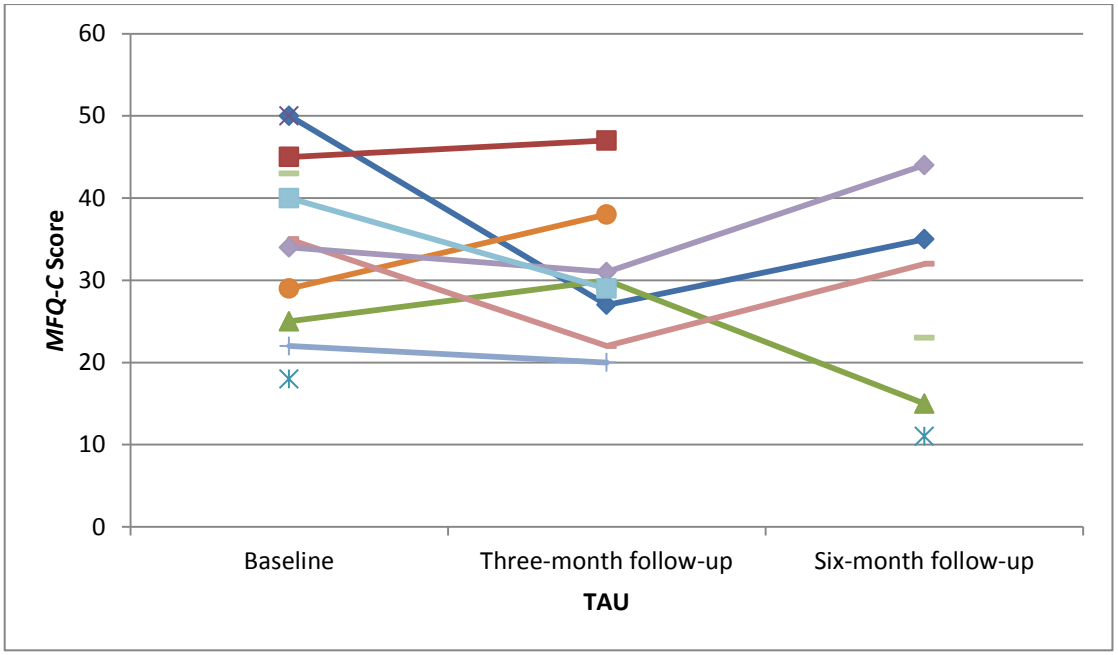


Figure 16: Participants in the TAU arm, MFQ-C scores at baseline, three and six-month follow-up (where follow-up data was available)

In a fully powered trial, to assess whether these trends reflect real associations or are the result of fluctuations caused by the variability in the data we would look at score by treatment group and report effect sizes using Cohen's d. Here the post-treatment group differences (at three-month follow-up) were therefore compared using linear regressions. Mean effect size using only the actual data collected (i.e. excluding participants who did not have data available at three-month follow-up) resulted in a moderate effect size with a Cohen's d of 0.78 (95% CI -0.29 to 1.82). If we conduct an ITT analysis using the LOCF method to replace missing values at three-month follow-up, the effect size based on a mean comparison Cohen's d was 0.31 (95% CI -1.15 to 0.53) indicating a smaller, but again moderate effect. This indicates on average those in the BA arm scored a third of an SD lower on the MFQ-C than those in the TAU arm. This means that those in the BA group reported, on average, less severe depressive symptoms compared to those in the

TAU arm. However, since the 95% CI crosses zero, we cannot say that there was a significant effect of treatment. This lack of significant effect may suggest that there is indeed no effect of the treatment over and above TAU, or it may reflect the small sample size in this study, meaning that the study was not sufficiently powered to detect a clinically significant difference in scores with 95% confidence that this observed difference is not due to chance.

An additional ITT analysis whereby MI was used to create datasets with imputed missing values at three month follow-up was also conducted. Following this, linear regressions predicting outcomes from treatment group for the imputed datasets were conducted and the results recombined using the MI regress command in STATA. Baseline MFQ-C scores, age, sex and service Tier were incorporated during the missing data modelling in order to inform the imputed values. That is, a missing data model was postulated under the 'Missing at Random' assumption, whereby the missing outcome values were related to the observed values at baseline, as they were for participants where the outcomes were present. Treatment allocation was not incorporated into the missing data modelling process because imputed values conditioned on allocated group may have overestimated the treatment effect. This is because it would be based on the assumption that those with missing data at follow-up outcomes would have had a similar treatment response to those with complete data. This assumption is not generally plausible, as those who drop out of treatment may do so due to reasons related to responsiveness. Thus, including group allocation when informing the imputed values is likely to have exaggerated any treatment effect. An ITT analysis was conducted for the MFQ-C scores using 10, 100, 300 and 1000 imputations; deciding upon 100 imputations as the results stabilised at this

point. It was clear from the results from the imputed datasets that there was a lot of uncertainty owing to the missing outcomes and relatively small number of observations.

Intention to treat analyses with multiply imputed data with all randomised participants from baseline to three-month follow-up (BA=11, TAU =11) showed an effect size based on a mean comparison of 0.74 (95% CIs -0.34 to 1.83). This is the value of the standardised regression coefficient (the raw beta was -7.07 which was then divided by the SD of 9.50) representing an average estimated reduction of approximately three-quarters of an SD on the MFQ-C for those in the BA vs TAU group. Thus, this value, analogous to Cohen's d (which could not directly be calculated in STATA for multiply imputed datasets) indicates a large effect of BA compared to TAU. It is unsurprising that the results from the imputed dataset present a more favourable estimate of the relative effect of BA than using LOCF. This is because LOCF tends to underestimate treatment effects, especially in this scenario, where the 'last observation carried forward' is the baseline symptom score. Thus using the imputed values likely gives the most plausible estimates of the true effect size, though it should be noted that the CIs around these estimates were very wide. At six months, the improvements appeared to be maintained in both arms; improvements in the BA arm were steeper (from 23.43 to 15.8) than those in the TAU arm (30.5 to 26.67). Average change in each treatment group at three and six-month follow-up has been plotted with CIs (Figure 17).

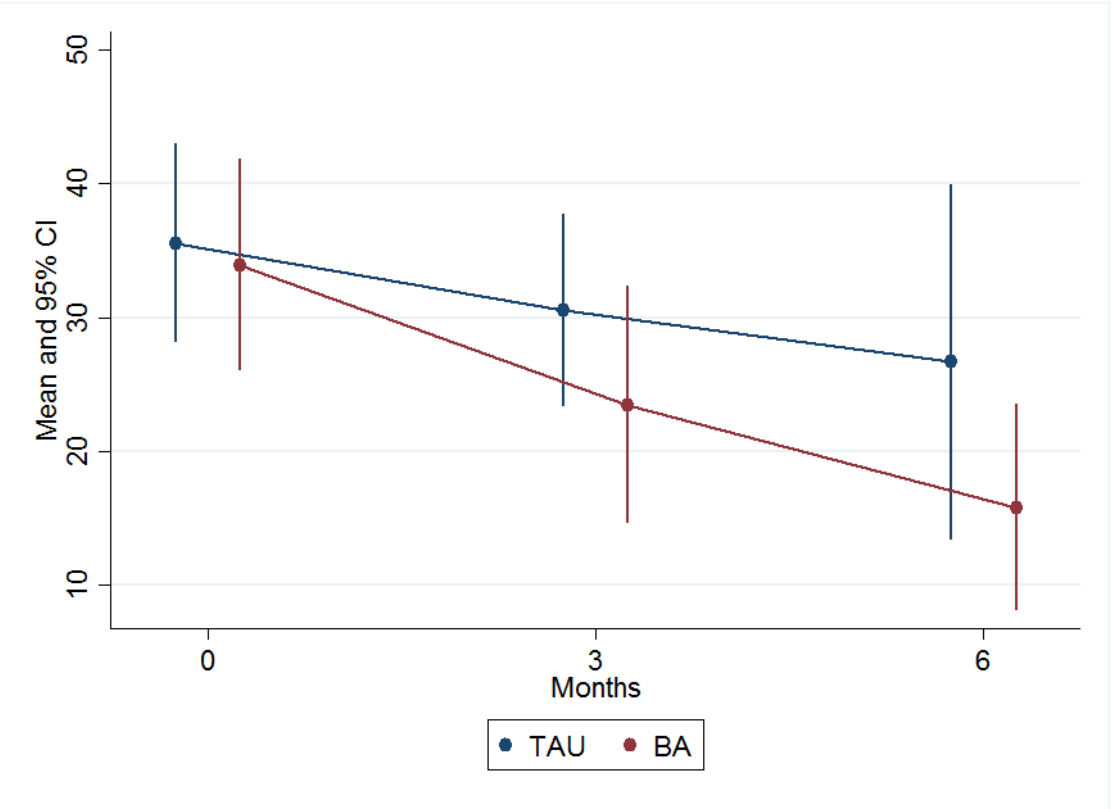


Figure 17: Average change MFQ-C scores across participants from each treatment group at three and six-month follow-up with CIs

Depression parent-rated symptoms at follow-up (MFQ-P)

Figure 18 shows a graphical representation of the average MFQ-P scores at baseline, three and six-month follow-up according to treatment group assigned (where follow-up data was available). Higher scores indicate worse mood. The numbers were even smaller on this variable than the child-rated version, due to parental ratings only being taken for young people under 16. Scores improved for both arms between randomisation and three-month follow-up, more so for the TAU arm (from 29 at baseline to a score of 26.6 at three-months) than for the BA arm (29.83 to 29.33). A linear regression was not conducted on the MFQ-P score due to the small numbers of observations and the large variability seen in the MFQ-C where there were a

greater number of observations. At six months, the improvement continued in the BA arm (29.33 to 11) but those in the TAU arm were not maintained (26.6 to 27).

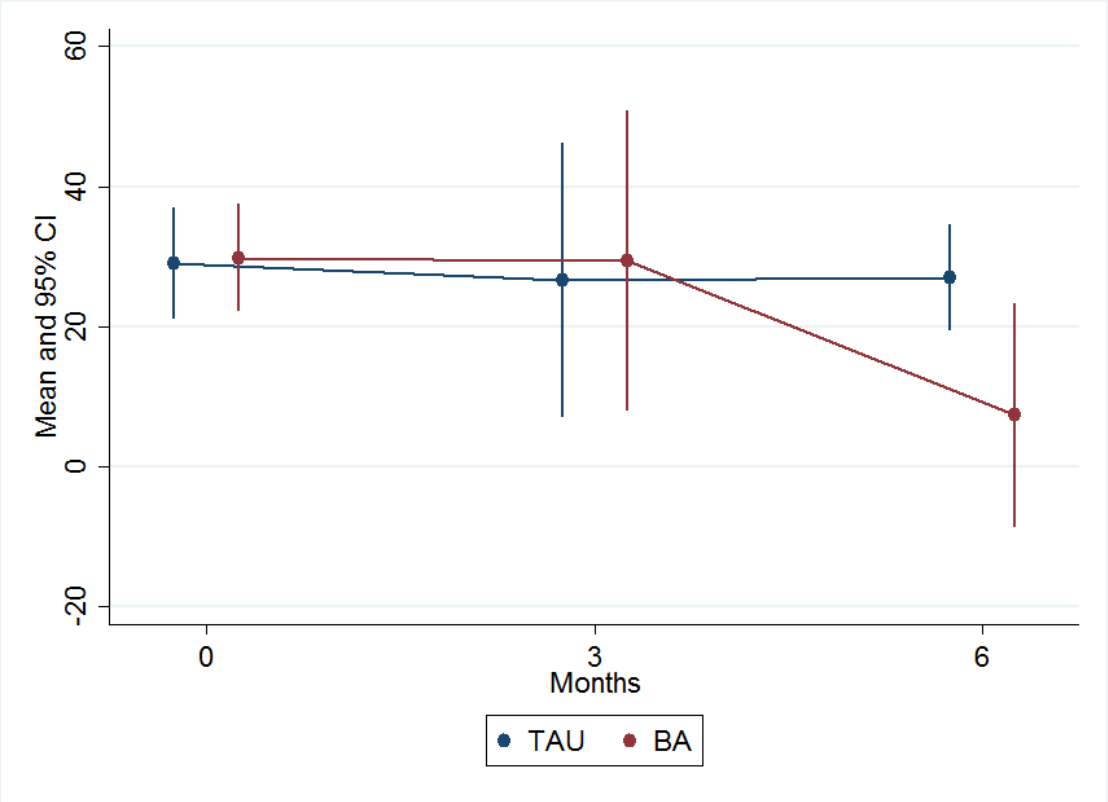


Figure 18: Average participant score on the MFQ-P according to treatment group at baseline, three and six-month follow-up with CIs

Self-Esteem at follow-up (RSE)

Figure 19 shows a graphical representation of the RSE scores at baseline, three and six-months according to treatment group assigned (where follow-up data was available). Lower scores indicate poor self-esteem with those below 15 suggesting low self-esteem. There is a trend in improvement in RSE scores in the BA treatment arm, indicating improved levels of self-reported self-esteem. The trend is the TAU arm appears to be much flatter, with a slight trend towards improvement. Scores improved for both arms between randomisation and three-month follow-up, more

so for the BA arm (from 11.09 at baseline to a score of 14.57 at three-months) than for the TAU arm (12.45 to 13.5). Mean effect size using only the actual data collected (excluding participants who did not have data available at three-month follow-up) was indicated by a Cohen's d of 0.23 (95% CI -0.79 to 1.25), indicating a modest effect on self-esteem. If we use LOCF to fill in the missing outcomes data, Cohen's d is 0.02 (95% CI -.82 to .85) suggesting a very small effect. If we use MI to fill in the missing three-month follow-up outcome data, Cohen's d is 0.24 (standardised regression coefficient 1.07/SD 4.44; 95% CIs -0.93 to 1.41) indicating a small effect. As seen in the MFQ-C results, using LOCF to account for missing data provides a more conservative estimate of effect size. At six months, the improvements appeared to be maintained in both arms; in the BA arm (from 14.57 to 15.8) and TAU arm (13.5 to 14.5).

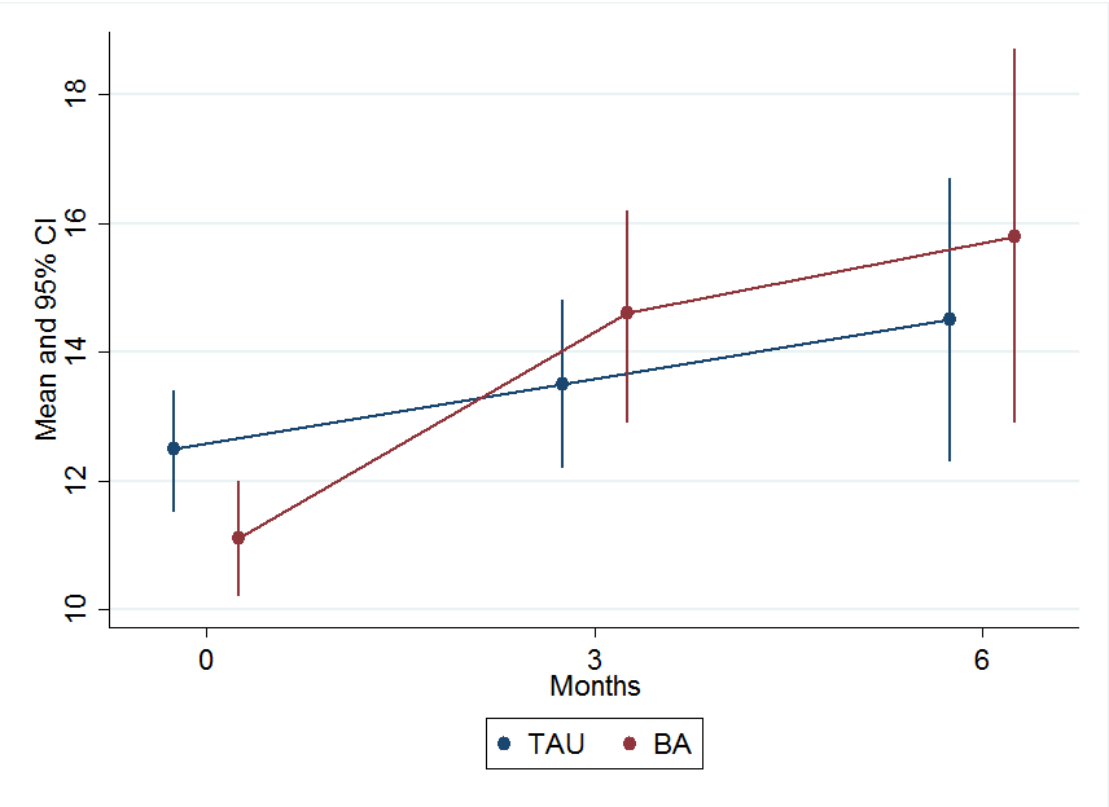


Figure 19: Average sores on the RSE measure are shown in the diagram below at baseline, 3 and 6 month follow-up with CIs

Functioning at follow-up (CGAS)

Figure 20 shows a graphical representation of the CGAS scores at baseline and three-month follow-up according to treatment group assigned (where follow-up data was available). Higher scores indicate improved functioning. There is a trend towards improvement in functioning in the BA arm compared to a trend towards lowered functioning in the TAU arm. Scores improved in the BA arm but worsened in the TAU arm between randomisation and three-month follow-up; BA arm (from 54.55 at baseline to a score of 65.29 at three-months) and TAU (59.64 to 56.63). Mean effect size using only the actual data collected (excluding participants who did not have data available) was a Cohen's d of 0.78 (95% CI -0.29 to 1.82), indicating a large effect size. If we use LOCF to fill in the missing data, Cohen's d is 0.43 (95% CI -0.43

to 1.27) indicating a large effect size. If we use multiple imputation to fill in the data, Cohen's d is 0.75 (standardised regression coefficient 8.66/SD 11.62; 95% CIs -0.40 to 1.83) indicating a large effect.

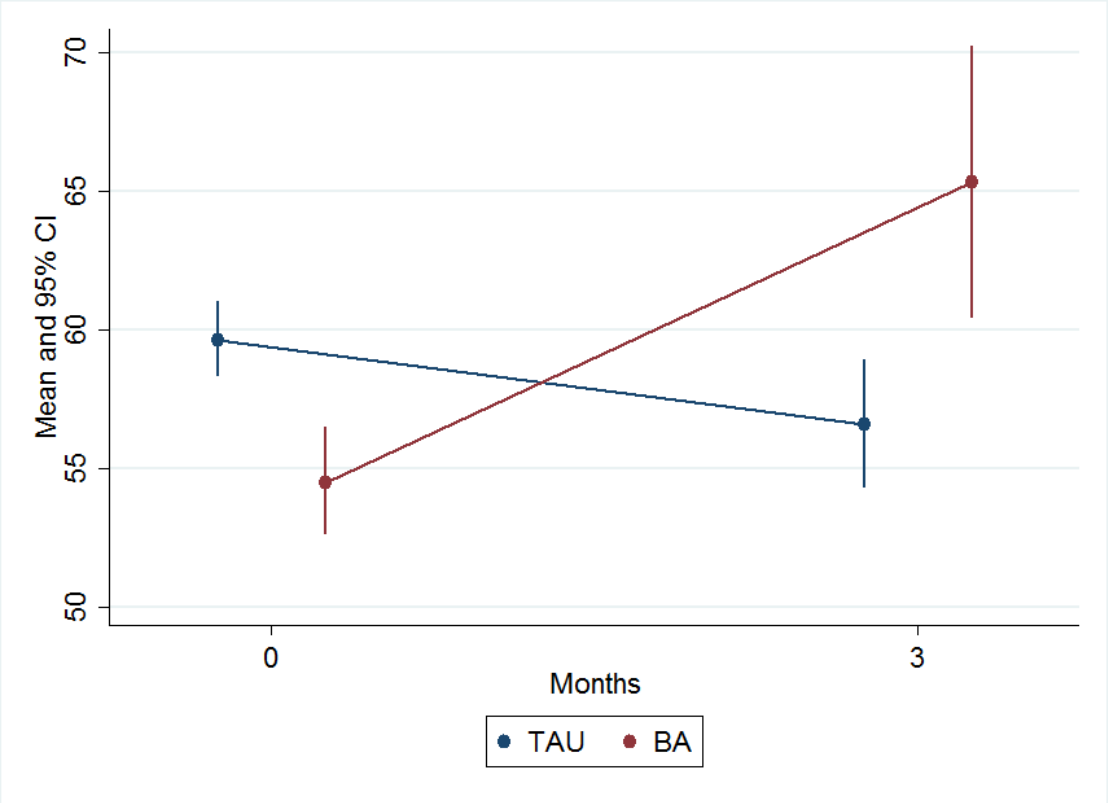


Figure 20: Participants allocated to BA or TAU with baseline and three-month follow-up CGAS scores where data is available showing CIs

Activation at follow-up (BADS)

Mean score has been compared between baseline and three-month follow-up. In the BA arm, there was a very slight improvement seen in the ability to complete tasks, in the TAU arm this was larger (BA: 2.57 to 2.43 [negatively scored]; TAU: 4.25 to 3.75), avoidance (BA [negatively scored]; 2.86 to 2.57; TAU 3.63 to 2.25), rumination (BA: 4.43 to 3.14; TAU 4.75 to 4), less likelihood of engaging in activities to distract from mood problems (BA: 2.71 to 2.29; TAU 3.63 to 3.13). On average in both arms young

people reported an improvement in the amount and type of activities they were undertaking (BA: 2.14 to 2.71; TAU: 2.75 to 3.13) and the number of activities they were engaged in (BA: 1.5 to 2.43; TAU: 2.38 to 2.5). In terms of their ability to make good decisions about what type of activities they did or the situations they put themselves into, a slight improvement was seen in the BA arm but not the TAU arm (BA: 1.86 to 2.86; TAU 2.75 to 2.38) and there was a similar finding for being an active person and achieving goals (BA; 1.71 to 2; TAU; 3.13 to 2.25) and enjoyment of activities (BA: 2.86 to 4.14; TAU: 3.88 to 3.75). Self-esteem had increased in the BA arm (3.86 to 2.43) but remained the same in TAU (3.13).

End of treatment survey

The results of the quantitative Likert scale responses are summarised in Figures 21 and 22 and the responses from the free-text boxes are discussed below. Seven young people from the BA arm and eight from the TAU arm (who attended the three-month follow-up interviews) completed the end of treatment survey with their accompanying parents.

Figure 21: Combination of feedback from both young people and their parents on BA and Treatment As Usual (TAU) using a four-point Likert scale relating to how helpful they found their treatment

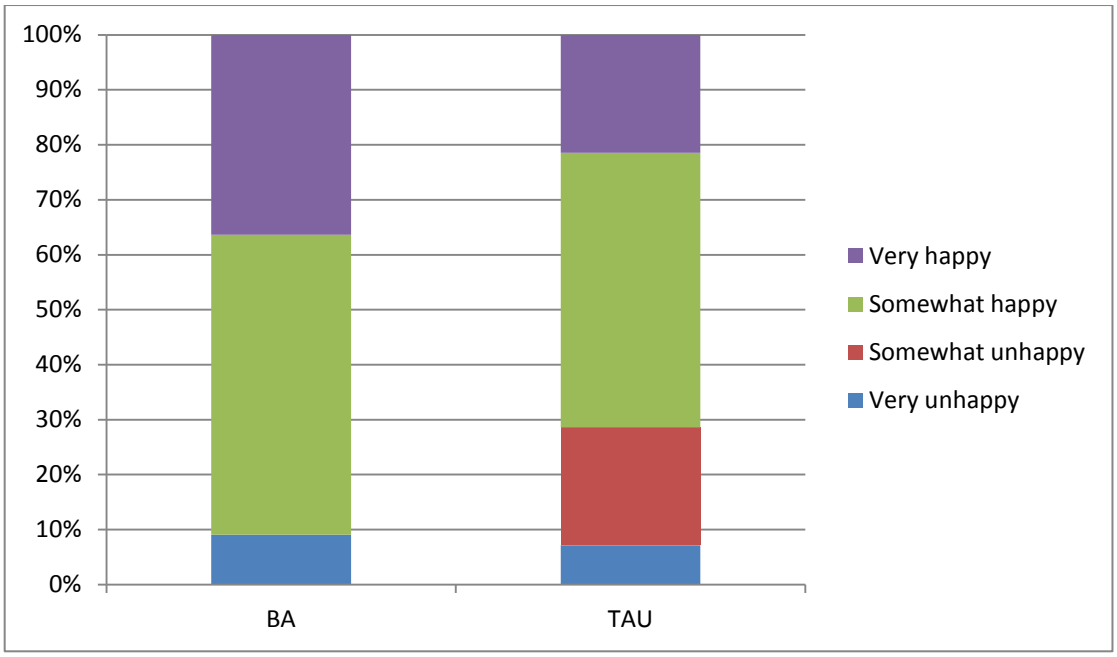


Figure 22: Combination of feedback from both young people and their parents on BA and Treatment As Usual (TAU) using a four-point Likert scale relating to how happy they were with their treatment

When those young people assigned to BA treatment were asked if they found the treatment they were offered helpful; five (5/7) reported BA was helpful to some

degree whilst one did not find it helpful (one did not receive treatment so could not comment). Three (3/4) of their parents found BA treatment to be helpful to some degree and one did not. See Figure 21 where the young person and their parent's responses have been collated and compared between treatment arms. In addition, free text box responses indicated one young person assigned to BA treatment valued that their feelings were acknowledged, they were listened to whilst also being given practical advice during their four sessions. One young person who received the full course of BA, liked that the approach was based upon them helping themselves rather than having to rely upon other people. Their parent found it helpful that BA focused upon things their young person used to enjoy and how they could revive these interests. They also noted that BA treatment was non-blaming; helping their young person to realise it was not their fault that they felt the way they did. Another young person, who completed the full course of treatment, felt that their BA practitioner was lovely and really helpful and that the BA treatment helped them a lot. This young person's parent liked the weekly format of the BA sessions. Another parent whose young person received the full course of BA, found the BA treatment easy to follow and understand. In response to the survey question asking if they were happy with the BA treatment they had received, six young people reported they were happy to some degree whilst one was 'very unhappy'. All four parents asked were happy to some degree with BA treatment (see Figure 22). Most young people and their parents did not have any negative comments about participating in the study or receiving BA treatment. One young person's parent commented they "didn't do much" in BA treatment after receiving two sessions. One young person explained how they didn't like "CAMHS in general" and did not like one of their

clinicians (although this was not the practitioner who delivered BA). One parent felt they already knew most of what was taught during the BA sessions.

Eight young people (and six parents) reported upon their experiences of TAU (see Figure 21). Five young people stated it was helpful to some degree and two did not find it helpful. One young person and their parent reported not receiving any treatment so could not comment. Three parents reported it was helpful to some degree whilst one did not find it helpful (one parent reported not being present during treatment so was unable to comment). In a free-text box, one young person reported it was helpful to have the opportunity to speak to someone about how they were feeling. One young person described how usual care had allowed them to identify their unhelpful behaviours. Their carer felt that treatment had enabled an understanding of the types of unhelpful thinking that can have negative impacts and provided the foundation for healthier mental habits. One young person valued that their clinician "took what I said seriously and were understanding". Their parent liked how the clinician asked for their young person's opinion and plenty of time was given to her at each appointment so there were no feelings of being rushed. Another young person commented that their clinician provided them with good ways to cope with their feelings. In contrast, their parent felt they hadn't yet received any treatment. Four other families reported either only having an assessment or no treatment to date. Despite their treatment not going ahead, one young person felt the process had improved their understanding surrounding panic attacks. When asked on the survey if they were happy with the TAU they had received, six young people reported they were happy to some degree whilst two were not. Four parents were happy to some degree whilst two were not (see Figure 22). One young person,

receiving usual care, stated that they had not heard from their clinician in a while. Their parent stated they needed to learn skills relating to how to manage their young person's mood swings and would have liked to have received more knowledge of what treatment as usual would consist of. One young person felt no care had really been offered other than "discussing things". Their parent felt it was unhelpful that they were never given an opportunity to speak to the clinician alone, as their young person was always present they felt they could not be totally open with CAMHS staff. One young person felt disappointed that they weren't able to bring themselves out of their low mood and their parent felt that the primary difficulty seemed to be moving from understanding at an intellectual level to engaging with the techniques in an emotionally meaningful way. The parent reported that there was an 'emotional disconnect' which made the benefits of treatment difficult to access. Another young person felt there was a lot of repetition in their TAU. Of those who received BA therapy, five young people and four parents felt they would continue to use the skills they learnt during treatment, whilst two young people did not. One young person did not feel like they could comment. Of those who received usual care, five young people and three of their parents felt they would continue to use the skills they had learnt during treatment, whilst two young people and one parent did not. In addition, one young person and two parents did not feel they could comment.

Fidelity measures

No session recordings were made as requested by clinicians in the randomly selected 10% of treatment sessions. As such the fidelity measure could not be deployed. This was either due to clinician error using the recording equipment or refusal by the patient or clinician to record the session.

Routine Outcome Measures (ROMs)

I planned to collect and analyse ROMs, however clinicians completed these inconsistently; some clinicians followed the CYP IAPT guidance closely using a minimum of one ROM per treatment session whilst others did not administer any. For this reason, there was insufficient data to provide a summary of ROMs.

Adverse events

No adverse events were recorded during the study period.

Summary of BUDDY trial quantitative results

The study sample was an adolescent population recruited exclusively from referrals to CAMHS. As would be expected, there was an overrepresentation of females. The sample was mild to severely depressed, with a high number of likely comorbidities, low-self-esteem and poor functioning. BA treatment resulted in favourable outcomes across a range of measures when compared to usual care. Although these between-group analyses were conducted post-hoc, and as such, were exploratory in nature. This is unsurprising as the number of treatment sessions in usual care were not controlled for and the descriptive summary suggested participants in the usual care arm received fewer treatment sessions. The results presented in this section indicate the acceptability of BA treatment to many young people, the outcome measures were able to be appropriately deployed and young people generally experienced positive treatment outcomes in terms of mood, self-esteem, activation and functioning. The following section will discuss the qualitative findings of the study.

Stage II Qualitative Results

Presentation of the results

This section presents the qualitative thematic analysis of interviews conducted with young people (alongside their parents in some cases) and clinicians. Interviews with young people, participating parents and staff allocated to the BA treatment arm explored their perceptions of their involvement in the BUDDY study, the feasibility and acceptability of the trial and the intervention itself.

Firstly, feedback on the format and delivery of BA therapy, a vital element of the acceptability and feasibility of treatment, is presented. This is followed by a contextual description of instances where young people did not receive the full complement of eight BA sessions. Secondly, families' and clinicians' treatment experiences and the impact of treatment is explored. The section concludes with an integrated summary of all qualitative interview results.

The same participant and staff pseudonyms have been used as in the previous results sections (see Table 8 for participant pseudonyms illustrated with a 'P' and staff pseudonyms in Table 9 illustrated with a 'S').

Data quality

Interview audio files were professionally transcribed verbatim, and transcripts were checked for accuracy against audio files prior to analysis. No transcription errors were identified. Attention was taken to use quotes in the language participants used, rather than editing to make quotes grammatically correct. This was felt to be

particularly important for young people to ensure the presentation of the data was an appropriate representation of their views.

Results

Format for the delivery of therapy

In order to inform the delivery of the intervention in a future trial, families and staff were asked about their preferences and experiences in relation to the layout and delivery of the BA sessions. The following section is presented under the areas that the interview topic guides followed; enquiring about the format, length, number and timing of treatment sessions and staff were also asked for their opinions on the format of treatment from a service delivery perspective. The desired degree and content of parental participation is then discussed.

Weekly format

Staff, young people and their families were all supportive of a regularly, weekly delivery structure. Although Jessica (P4) did not complete any BA sessions, by drawing on prior treatment experience she suggested that the format of the weekly sessions would be appropriate:

> "I think I'd had the monthly [format] when I was in year 10, and I felt like too much happened and I felt too differently every month to go through it properly. So I think weekly would have been quite helpful had I still been in the place that I was when I first decided to do [the study]. Because yeah I did feel like a lot was changing with me every week, and I was feeling a lot of different things, so yeah it would have been helpful"

Two parents reported satisfaction with the weekly format of sessions, one of their children (Frankie P2) also reported that the length and weekly delivery of sessions was suitable. Another parent and their child (Estelle P5) felt that the weekly format was more successful than a longer duration between sessions because it made it

easier to remember what had been happening in the young person's life, and enabled them to reflect upon the success of goals that had been set during treatment. This information could then be used to effectively inform the BA treatment session. Similarly, Lucy (P6) also found the weekly format useful to achieve her treatment goals but would not have wanted to have had treatment sessions more often than once a week:

> "I think the length was pretty good, because we could work through what had happened in the previous week. And also what should happen in the next week. So I think it was a good amount of time"

> "I think a week is probably the shortest it could have been. Maybe a week to three weeks separately, but I think a week was pretty good"

David (P3) reported that he did not receive his BA sessions in the prescribed weekly format, but that a weekly format would have been preferable:

> "I had [BA sessions] all over the place. Like I would miss a session for three weeks because no one was there to, like [Sharon S5] wasn't there, she was on holiday or something, and I think that sort of affected the entire experience"

> "…there was long periods of time where I didn't have a session, and I think that sort of messed it up"

David noted these gaps between treatment sessions were to the detriment of his depression treatment.

Staff echoed the sentiments of the young people and their families above, feeling that a weekly format was suitable:

> "[Having a week between treatment sessions means]…you can make progress. A week is a long time in therapy" [Nicola S2]

> "I think having more than a week between our sessions they remember even less of what we talked about" [Shane S3]

Another staff member (Paul S4) commented that after he had become familiar with the manual materials, he felt the treatment "just seemed to flow" due to the regular format, with a week in between each session seeming appropriate.

Treatment Session Length

The treatment session length (of up to an hour) was viewed positively, but young people and clinician's suggested adaptions could be made. David (P3) felt that each treatment session was too short and reflected on whether or not this may be the case for other young people or whether his Autism Spectrum Disorder (ASD) comorbidity may have had an impact upon his ability to engage with his therapist:

> "… I find it very hard to speak to people and it's, and when you're sort of just sitting there with somebody it's hard. Like it's hard to explain to someone how you're feeling, so like the amount of time you're given"
>
> "…I don't really know how you can sort of explain a lot of things and get across to somebody in half an hour"

David (P3) found that he did not have enough time to become comfortable with his therapist during the short sessions; he estimated his average session length was 30 minutes but he would have preferred each session to last around 50 minutes. The treatment session length was confirmed in David's case notes, varying from 30 to 45 minutes, with an average of 32 minutes. As previously mentioned, this young person was suffering from an ASD, which may have affected his ability to open-up during treatment sessions. However, another young person (Frankie P2) who shared David's ASD comorbidity felt the length of the sessions was acceptable. A further young person, Estelle (P5), also felt that the length of each session was ample.

Shane (S3) reported that from a staff perspective there was too much information to work through in certain sessions. Staff stated that the session length

was suitable but that the manual materials needed to be reduced for some sessions to be delivered within the one-hour timeframe:

> "There was, I think it was week five or six… about 13 pieces of paper that you need to take. So worksheets, information sheets, parent sheets, outcome measures, and I think that's, I mean I'm big on outcome measures, I think they're fantastic, but I think 13 pieces of paper is a bit much. Even for the kids who are well engaged and the kids who go to school and are used to coming home with piles of paper, they don't want 13 pieces in an hour" [Shane S3]

> "…one of the [session] packs was very long and it was a bit of a race to get through it" [Nicola S2]

This feedback suggests there is scope for the manual materials to be further refined. In fact, some clinicians and young people felt the manual acted as a barrier to treatment for this reason, which will be discussed in further detail below.

Number of treatment sessions

Most young people did not report that they required a greater number of BA sessions. One young person for example, David (P3), felt he had received an adequate number of treatment sessions. Lucy (P6) also found she had received a sufficient number of sessions:

> "I think it was about just right. It was enough time to work on one certain thing and then have another step to go through, and just enough where it got to the point where I could start to help myself a lot more"

For some families, however, the number of treatment sessions was not sufficient. Estelle's (P5) family identified that the number of sessions had been helpful in treating Estelle's depression but that she needed more time to focus on her anxiety. Estelle's clinician Nicola (S2) seconded these viewpoints and did not feel that BA had been useful in addressing Estelle's generalised anxiety, although it was not clear

whether this was due to the content of the BA treatment or the limited number of treatment sessions:

> "There's ingrained stuff with [Estelle P5] about generalised anxiety that BA wouldn't shift, because she needs something longer. Perhaps even later she could do with medication of some sort, because it really was ingrained stuff that she had" [Nicola S2]

Estelle's parent suggested further BA treatment to address anxiety could take the format of group sessions but Estelle contradicted this view, as she reported she would feel more comfortable receiving individual treatment sessions. Comorbid conditions, such as anxiety, were felt by many families and clinicians to represent a barrier to successful treatment that will be discussed in further detail below.

There was mixed feedback from staff members in relation to the optimum amount of treatment sessions. One staff member, Sharon (S5) felt the number of BA sessions was adequate. For other staff members, the number of treatment sessions should be decided based upon the individual client. When reflecting upon the treatment of a complex family (Victoria [P8]; who did not attend follow up so was unable to be interviewed), Paul (S4), reported that it took several sessions to identify and target ingrained avoidance behaviours and so concluded that the flexibility to have more sessions if necessary may have been useful. Another clinician, Geoff (S1), indicated that the number of sessions was appropriate to the needs of the young people, but not the needs of the service in terms of the pressure stemming from waiting lists for access to the service, the demand for and the capacity of the service to provide treatment.

> "I think that one of the difficulties was in terms of the eight sessions, and whether that was, was that, it was appropriate to need but could we justify that amount of time if we were applying that to a number of different cases, because that would have severely impacted or would

> severely have impacted upon our capacity in terms of addressing that demand. And that's where the pressure is at the present time" [Geoff S1]

This is reminiscent of the issues with capacity observed during the ethnography in Stage I of this research. Further to this, as well as difficulties in delivering manual content within the one-hour treatment session noted above, it was also difficult for staff to cover all of the concepts within the manual in the number of treatment sessions provided. Shane (S3) reported difficulties in delivering the manual material within the eight allocated BA sessions:

> "For the content that we were provided with, the number of sessions was nowhere near sufficient. Particularly working with I'd say the more internally focused teenagers… we did stick to the eight sessions and a follow-up. But unfortunately we were forced to miss some of the manual out. It was I suppose yeah, it was just quite tricky"

Shane highlighted the need to make his own adaptions to the manual to fit the BA treatment into his usual practice.

Timing of treatment sessions

Most families chose not to comment upon the timing of their treatment sessions, however for one family accessing treatment sessions on a regular basis presented difficulties. Estelle (P5) and her family felt that it would have been helpful if the BA sessions were offered after school rather than only being available during school hours:

> "Coming out of school sometimes, sometimes I think it could be aimed more for after school than having to drag [Estelle] out of school every week. Phoning the school and saying that [Estelle] had an appointment that was getting like… [pulls face]" [Estelle's [P5] parent]

> "The school don't know I come here. They just think I have a lot of doctors' appointments" [Estelle P5]

Highlighting the need for a broader consideration of the professionals involved in the young people's care when organising therapy delivery. Furthermore, the family

suggested that parental availability should also be assessed, with Estelle's (P5) parent commenting:

> "I think it was, the reason why we managed to get to them all was that we organised them so that it fitted in with us. And it was fine because I only work two days a week. I would imagine that people who work full time may have problems getting the time off to come to sessions"

These comments focus upon how the CAMHS service is delivered, rather than the BA treatment specifically, although they offer insight into the preferences of families. However, more relevant to the specific delivery of BA, Estelle (P5) and her family felt that it was difficult to go from a weekly format to no sessions at all:

> "The thing is now it's done, we don't know, we're pretty much in the dark of what we're going to do now, and how [Estelle] feels about, because she's got no more counselling sessions or anything. It just feels like right that's it, get on with your life now" [Estelle's [P5] parent]

> "…for that type of thing I think it was enough. But I'm just wondering what's going to happen now if you know what I mean" [Estelle P5]

This suggests staggering the final sessions or providing top-up or follow-up sessions may be useful to reassure families and provide continuity of care.

Service Delivery Considerations

Geoff (S1) questioned in a service context where BA would be best placed to sit; whether it would be in the prevention, early intervention or specialist element of the service. Staff suggested BA may be best placed as an additional psychotherapeutic tool, alongside other treatments in clinical practice or that other treatments could be used as an adjunct to specifically target comorbidities. Sharon (S5) probed whether BA should be delivered in its current format or integrated into existing approaches, stating the overall BA approach:

> "[BA] is quite a good idea that you can incorporate into other therapies, but I found it as I say very restricted and long drawn out to do it as a complete therapy" [Sharon S5]

> "I think [BA] made some difference, I'm not sure, because [Estelle P5] had generalised anxiety, whether it was going to be the only method to use on her" [Nicola S2]

> "Treatment did what it could, but she [Estelle] probably needed CBT, working longer on thinking errors possibly" [Nicola]

When asked what it was about CBT that may be more beneficial than the BA approach, Nicola (S2) said:

> "I think the two could be done together. I just think there needs to be a component where you really look at the way you think… I think BA has a really good use for low mood, not ingrained behaviour such as generalised anxiety, maybe that could be part of it, but it's a very useful component to use"

Nicola reveals a reliance upon cognitive approaches that focus more upon changing young people's thought patterns, such as CBT that aims to redress young people's 'thinking errors'. This may indicate a lack of therapist equipoise in that, the novel BA treatment was not viewed as positively as existing treatments for depression used in the service. Therapist equipoise is where the clinician holds no preference or knowledge for choosing one treatment over another, which could be a source of bias in the trial if Nicola has more confidence in the treatments provided as part of the usual care arm. Shane (S3) felt the prescriptive nature of the manual was not the best approach to utilise in a CAMHS setting, and wondered if the session time could be better utilised by incorporating suggestions for agenda items directed by the young people. He highlighted the difficulties implementing BA in a manualised format and how this may be at odds with the usual clinical guidance:

> "The other gripe that I want to throw in is thinking about service user choice I think is really important. And I think in being quite prescriptive

> with this, is the amount of sessions you have and this is the layout of them. The first activity for every week is agenda setting, and if you've set an agenda that has 13 items of worksheets that you need to go through, and the young person says well actually I've had a rubbish week, you'd lose all the scope to do that therapeutic work and to build on that therapeutic alliance. I think if you're going to have a very strict, very prescriptive and manualised therapy there's absolutely no point pretending that it's collaborative and that it's service user informed. Prescriptive and collaborative are two very different things. Sorry, rant over" [Shane S3]

Unpacking whether this dissatisfaction lay with the treatment manual format or the concept of a manual itself will be vital to the future implementation of the treatment. This concept has been discussed in further detail in Chapter 5 in relation to how it could be explored in future research.

Parental involvement

The degree of parental involvement in young people's treatment was important to explore, as this may have affected the young person's treatment experience or engagement. There was no clear consensus across the interviewees about the optimum level of parental participation in treatment, but, with the exception of one case, there was agreement between most parent and child dyads about what worked for them as a family, highlighting the importance of service user choice in therapy.

Preference towards more parental input

David's (P3) parent felt that the fact that David attended the BA sessions on his own provided independence for him, but also found it represented a barrier to providing appropriate parental support during his treatment.

> "…I was saying to [David] when he came home… what's your homework for this week? Nothing! And I never knew whether he did have homework or he didn't, what tasks he was supposed to fulfil… and then I'm trying to motivate him to go out. And I didn't know if it was constructive or not"

> "And I just thought it was a nice thing for [David and Sharon [S5] his therapist] so I sort of stepped away. But at the same time because I've been involved in most things I would have rather she'd phoned me about something and what they do. Because people, I mean people with… [ASD] notoriously keep things to themselves, and if you don't want to talk you don't want to talk to us do you [David]? That's it, dismissed, and I'm dismissed"

David's mother suggested that due to his ASD, David only conveyed a limited amount of information about his BA sessions to his parent. As such, his parent required additional information from David's therapist, Sharon (S5), about the content of his care plan. Having limited knowledge about David's treatment content led to a lack of faith in the prescribed treatment. The parent suggested that a phone call between parents not involved in the treatment and the therapist would be beneficial to counter this limitation, or alternatively, the young person's between-session homework tasks could be written down and shared with the caregiver. Sharon agreed that greater parental involvement for David may have been advantageous:

> "My client didn't choose to bring his parent…but I can perhaps see how that would have been helpful because the parent could have encouraged the client and could have helped the client understand some things"

As was the case for Sharon (S5) above, the utility of parental involvement was recognised by other clinicians. The level and format of parental involvement had to be determined by considering patient preferences. This represented a challenge on occasions where the therapist recognised the need for parental involvement, but the young person did not. Shane (S3) commented:

> "I think involvement of parents would have been helpful. I think it's a tricky one because [Alicia P11] specifically didn't want parents to be involved in the sessions. But I think acknowledgement of parents, [she was] quite dependent on parents, and I think parents reinforcing that, it would be useful if you did this, would have made a huge difference"

> "I mean with the service user I was working with they didn't want parents involved in their therapy sessions, and they were very closed around parents; however were happy for me to see parents separately. Now how that fits into the eight session model I'm not sure"

Another families' clinician, Paul (S4), felt the level of parental involvement could be strengthened and the materials for parents could be improved. One suggestion was

to introduce a weekly briefing for parents about what their young person and the therapist had been working on. Paul highlighted his work with Victoria (P8) and the role her parents played in maintaining Victoria's depression, and the difficulties of engaging her parents in treatment. Often her parents would drop Victoria outside of the CAMHS centre and refuse to come in. Paul felt the parental role in therapy could be tailored to improve the support parents provide to their young person, rather than being focused on more general skills, such as communication. Paul provided the example of Victoria's parents thinking it was completely normal for their daughter to spend all night in her bedroom and how they had inadvertently been encouraging low mood behaviour. Paul suggested the family needed to be directly involved in Victoria's care, in order for her parents to provide her with appropriate and well-directed support in improving her depressive symptoms. Again, the commentary above highlights that there will not be a 'one size fits all' approach concerning parental involvement.

Although clinicians and one parent felt more parental input would have improved the delivery of BA, there were no young people who suggested they would have preferred more parental involvement. In most cases where parents were involved in young people's BA sessions, young people were content with the amount of parental input and could identify benefits stemming from this collaboration.

Benefits of parental involvement

Frankie (P2) requested that their parent attend all their BA sessions. Frankie found this helpful because their parent was able to remind them to employ the skills learnt during treatment in their everyday life. Lucy (P6) and her family reflected upon the benefits of BA treatment with parental involvement:

> "I think personally because of what had happened I was quite detached from my family, so at first I didn't want them to be involved. But I think maybe part of it should be getting back the attachment of normal things"[Lucy]

> "I found it better when [Lucy] was talking more with us at home, and I think the way that she was, was improved when that happened more as

well" [Lucy's parent]

Lucy was comfortable with her parents being involved in her BA treatment but suggested this involvement was most useful towards the end of treatment to help her trouble-shoot barriers to goal-setting and activity scheduling. Staff recognised the importance of collaborating with parents and considered it to be crucial to treatment success:

> "Getting the parents on board was really important. That was very good. I can imagine if you didn't have a parent that was on board that would be a lot harder. So you're relying on parents to be on board" [Nicola S2]

> "[Estelle's [P5] parent] was sort of sent, you know, it was BA gold really, she was sent from heaven and she was a perfect angel. Very obedient, was on board, yeah I just couldn't fault her" [Nicola]

When Nicola reflected on the involvement of Estelle's (P5) parent during the BA sessions she felt the parent's enthusiasm and support was a key facilitator for Estelle's improved mood.

Despite these positive aspects of parental involvement, some young people chose to highlight either potential, or experienced, difficulties with their parents being involved in their care.

Difficulties with parental involvement

The desire of David's (P3) parent to be more involved in his care, was not echoed by David himself. David's reluctance to have his parent involved in his treatment was questioned by his parent during the qualitative interview, and it was clear from this exchange that their perspectives differed on what constituted 'success' in therapy. Between-session tasks were a particular challenge, where the tasks agreed between David and his clinician, Sharon (S5), were not valued by his parent. This was illustrated when the parent/child dyad were discussing a recent chance meeting between the David and an old friend:

> "One of the brilliant things that we did on the way back, we bumped into a lovely boy that [David] used to know at school…Neither of them spoke a lot, but he just seems such a lovely boy. And they've swapped numbers getting off the bus coming here. And they went out, which was brilliant.

But [David] has not contacted him since" [David's parent]

The parent felt this was an opportunity David had not taken advantage of to connect with an old friend, whereas David retorted:

> "The thing is… I'd have felt compelled to talk to him, and when we used to hang out we didn't talk a lot. We were just on the computers and we were just sort of, sometimes make like a conversation with each other for like a few seconds and go back on the computers, and you can't really do that. You feel compelled to talk to somebody"

David pointed out he had completed the between-session task he had been set by Sharon (S5), which was to speak to the friend over the phone. But it was not the task his parent would have preferred, which was meeting in person. This implies a possible advantage of a lack of parental involvement, in that the young person can focus on their own values and aims during treatment (a central objective of BA treatment), rather than their parent's priorities. It also illustrates the difficulties that arise when young people can identify 'depressed' or 'unhealthy' behaviours, such as sitting on computer games or not communicating with friends, but their uninvolved parents have not learnt the same lesson, due to them not being present during the BA treatment sessions. These instances are illustrative of how worldviews can differ between young people and their parents; in David's case, on the desired qualities of a friendship. Jessica (P4) who did not receive any BA treatment, expressed it thus:

> "I think it would have depended on what relationship people have with their parents. Because I know that I would be fine with my parents being involved, I think I would feel quite uncomfortable because they'd be listening to me talking about things to do with [my sister] that are very personal. And then I've had previous issues with my Dad… It's hard because I would rather keep him out of it when I know that my relationship at the moment is fine with him. But then in general I wouldn't mind them being involved. I think I just felt that I was fine to talk about it on my own, and then keep talking to them and informing them at home, but also it's a nicer way to talk about because it's an overview, they don't have to see me going through it if you get what I mean"

Jessica (P4) focused upon the stresses related to revisiting past events whilst parents were present, and her concerns about the impact this may have on current relationships within the family. She also highlighted the difficulties young people

might have when translating the dialogue following therapy sessions to parents at home who are not involved in their treatment. Other families also encountered the discomfort of discussing sensitive issues during BA therapy sessions:

> "I liked [my parent] there some of the times. Some of the times it was just a bit like she doesn't, I don't know. It's like she knows what to say but it's not hundred percent correct, do you know what I mean?" [Estelle P5]

> "I felt like I didn't want to be there sometimes. I did. Most of the time towards the end I would have, I think I went in for about the last four or five sessions, and I don't think I needed to be there. I'd rather, because I feel like [Estelle] clams up when I'm here and she won't talk. So I feel like I was going in time and time again, I felt like it was wrong, I shouldn't be… And then if she wanted to talk to me when she came out then I'd be there, but I'd rather not have been in the sessions all the time" [Estelle's parent]

Estelle's (P5) parent felt that her reticence to be involved, stemmed from a feeling that Estelle, and other young people, would be more open with her therapist without a parent being present. Both Estelle (P5) and her parent reported being worried about disclosing information during treatment sessions that would be upsetting for each other. This suggests parental involvement can be a barrier to the young person engaging with the treatment. Estelle's therapist (Nicola S2) reflected on her experiences with patients outside of the BUDDY study, stating that on some occasions parental involvement was unhelpful because she had observed mental health problems and coping styles run in families, leading to parents maintaining their young person's problems. This presents a dilemma in terms of how best to involve parents in future iterations of the BA manual. Although Shane (S3) felt increased parental involvement in Alicia's (P11) care would have been helpful, he also anticipated this may have presented problems in itself:

> "I think the difficulty with involving a parent in therapeutic work with a child and young person is always going to be the issues that the parent brings to the table. And I think it was really difficult in my session with the parent who brought their own mental health concerns with them. Some of the hour that we spent together had to be around helping them identify what was a realistic expectation, what was an understanding of the young person's mood dropping and what was their own anxiety around the young person's mood dropping …. And in essence integrating that into your sessions would be combining high levels of low mood, high

> levels of anxiety in two people and then trying to direct it all into one behavioural approach. I think [it] would be a nightmare, depending on the parent of course"

This highlights the perceived detriment of families bringing their own mental health concerns into their young people's treatment sessions. It also relates back to earlier sentiments where some clinician suggested the flexibility to have more BA sessions would have been advantageous. It also represents a barrier to the young person's treatment, which is likely to be outside of their control.

From a staff perspective, Geoff (S1) reported variable parental involvement; in one case, he worked with a parent who he felt was very committed (Lucy P6) whereas in the two other families, the parents were less dedicated in terms of their engagement (Connor P9; Neive P10). Geoff pointed out that although some parents were less actively engaged in their young person's treatment sessions, they remained committed to their young person's recovery, which appeared to be more important than the level of actual involvement. The most important factor for Geoff was whether or not the young person was progressing and moving forward with treatment. Although he recognised the role that parents played in supporting the young person to maintain the changes made during treatment, he felt this was not a central issue to the implementation of the provision of BA. It may be significant that this clinical viewpoint differed so markedly from his patient, Lucy's perspective that her parent's involvement played a key role in her life returning to "normal" following BA treatment.

Deployment of Behavioural Activation

Interrupted treatment pathways

One of the ways to assess the feasibility of a novel treatment option is whether it can be delivered as intended: this was also explored during the qualitative interviews with staff, young people and their families. The criteria for what was considered premature termination of treatment was different in the qualitative verses the quantitative sub-chapter. In the qualitative section, the threshold was anyone who did not receive eight sessions, in order to explore the reasons provided for termination of treatment. In contrast, in the exploratory statistical analyses one session was considered to be an adequate 'dose' of BA treatment (as the BA model is discussed and an individual formulation identified during session one). In some cases where individuals did not receive the full complement of treatment sessions, participants did not attend the qualitative interview so information was obtained from the participant's case notes (via the electronic records system [PARIS]) to provide information relating to their treatment pathway. Information from patient case notes was also valuable to contextualise young people's arguments. Each young person's treatment be discussed as an individual narrative drawing from interview and case note data.

Patient did not receive BA: treatment was not started due to patient's non-attendance

Jessica (P4) did not start her BA sessions, and explained that this was due to her and her parents initially forgetting about the therapy appointments. When the family realised they had missed these appointments, they contacted their clinician (Paul S4) to rearrange the sessions. As Jessica was about to turn 18, she would not have been able to have a full course of BA prior to being discharged from the service and when this was discussed with her, she felt she had improved enough to not warrant

treatment. Jessica felt this improvement was mainly due to a change in family circumstance that had improved her home life.

Another young person, Sophie (P7) did not start her BA sessions with Nicola (S2) as she was removed from the study by the CAMHS team. When Sophie came into the CAMHS service, during the study recruitment period, she was deemed to be relatively low risk and was assigned to treatment in Tier 2; however, during her first BA session she disclosed further information, which meant she was considered to be a much higher risk patient. At this point, she was transferred to Tier 3 for treatment by the specialist team, but could not be randomised within the BUDDY study because the patient needed to be allocated to the first available clinician (i.e. not necessarily a clinician involved in the trial), and as this treatment was required urgently, she no longer met the study inclusion criteria. In light of this, Sophie was not contacted by the research team again.

Patient received two sessions of BA: treatment was stopped prematurely by clinician

The clinician (Bridget S6) ceased BA treatment prematurely due to concerns over Jennifer's (P1) capacity to continue. Treatment was stopped whilst the IQ of the young person was assessed (there were particular concerns over her processing speed). Although patients within LD services were excluded from participating in the BUDDY study, it may be that a minimum intelligence level or reading age may be required to engage with the study materials. The perspective of the young person as to why their BA therapy ended was that they were too tired to engage in treatment. Unfortunately, Bridget, the clinician responsible for treating Jennifer, was unable to be interviewed due to her heavy workload so was unable to offer an additional perspective. This in itself, may be indicative of a potential barrier to the clinician delivering BA as intended; namely, that Bridget lacked the time to provide treatment

as directed and instead, looked for opportunities to deflect the onus onto other clinicians (i.e. the clinician responsible for assessing IQ). This would seem reasonable in light of the findings of the *non-clinically orientated variation in practice* theme from the focused ethnography that indicated clinicians provided care that was easily available rather than based upon an individual's needs when the service was under pressure. However, according to the case notes made by Bridget, Jennifer engaged well during the initial session and "seemed to have a good grasp of what BA was about". During the second session, Jennifer was described as unfocused and tired. She had not achieved the goal that had been agreed with Bridget, which was to make a new friend whilst away on holiday. However, this goal did not meet the requirements of a BA goal that should be SMART (Specific, Measurable, Achievable, Rewarding and Timely), a topic that was covered during session 1, and which should have been addressed by the clinician when the goal was being set. As this had not been done, it had to be attended to during the second session. In session three, Jennifer was described as more alert than previously but could not remember concepts discussed during previous sessions, so the manual content from session three was not delivered. Another possibility is that Bridget had not received adequate training to deliver the treatment appropriately, although this was unable to be assessed as the treatment session was not recorded. Bridget did not believe a BA approach would be helpful for this patient and terminated BA treatment at this point. Again, this hints at some staff members perceiving the BA treatment as less adequate than other available treatments. Subsequently, however, the IQ (and processing speed) of this young person was found to be within the normal range.

Interestingly, the patient in the case discussed above was the young person of the previously mentioned parent who would have preferred hypnotherapy as a treatment option, due to the level of engagement and mental resource required to engage in treatment.

During his interview, Geoff (S1) reflected on the care of Connor (P9; who declined the offer of a qualitative interview) who only received four sessions of BA.

Connor was described by Geoff as having “quite a heavy overload of oppositional defined conduct disorder type behaviour” combined with being “less articulate, less intelligent”. The clinician used this seemingly derogatory language with the caveat that it was not meant in a demeaning way, rather, the clinician was attempting to articulate the difficulties this young person faced in engaging with him. Geoff reported the structured format of therapy was difficult for Connor, particularly the concept of the between-session tasks. Geoff was, however, unable to unpick the reasons why this patient struggled to engage with the treatment (i.e. whether or not this was due to a lack of cognitive ability). When this reflection is considered alongside the case of Jennifer (P1) above, it suggests that intelligence was perceived to be a barrier to young people’s participation in treatment by their clinicians. The case notes Geoff produced for Connor’s BA sessions illustrate the difficulties of working with a young person who is conduct disordered, and also the challenges that young people face in their daily lives. In the week between Connor’s assessment session and first BA session, Geoff learned that Connor had received a temporary exclusion from school due to an altercation with a teacher. Despite this, Connor engaged well during the BA session, alongside a family member, and utilised his between-session task to address his behaviour in school by using a ‘time-out card’. The time-out card enabled Connor to remove himself from his lesson when feeling agitated and offered the opportunity for him to seek out help from a school Support Worker. When Connor attended his second appointment, he told Geoff he had been permanently excluded from school and there had also been a medical emergency within his family. The BA session was unable to be completed due to Connor bringing two of his friends to his appointment. When session two was rearranged, he

attended with a family member who reported some improvement in Connor's behaviour at home and Connor described distancing himself from his friendship group, who he felt were a stimulus for his anti-social conduct. At session three, he attended with another friend (despite being specifically asked to only bring an adult family member or to come alone); he had been unable to complete his between-session task because of having to move out of his home due to the earlier family medical emergency. At this point, Geoff and Connor had a discussion regarding the direction of treatment and Connor reported his mood had improved so decided he would not need all eight sessions. He did attend session four with a family member, where further anti-social behaviour was reported. Connor was offered a fifth BA session but did not attend his appointment or respond to a follow-up letter so was discharged from the service. Again, this highlights the complex population involved in the study, the requirement to be psychologically prepared to engage in treatment and the impact of a turbulent home life on treatment. This raises a broader issue in whether or not such rigid treatments are ever going to be able to adequately respond to the complexity of the target population.

Geoff (S1) also reflected upon working with another client, Neive (P10; who was uncontactable for the qualitative interview), who only received three sessions of BA before withdrawing from treatment in favour of the families' request for Neive to be assessed for medication. Geoff wondered whether intellectual ability or motivation to change was what presented a barrier to her care:

> "I think it's about the issue of commitment isn't it? Where it worked well the people were committed; where it didn't work so well was in that young person who felt less or possibly had more difficulty in being able to record what they did. Now whether that's about motivation or whether that's about cognitive ability, I don't know"

The case notes for Neive again show the complexity of working with young people. Neive attended session one alone and according to Geoff, appeared engaged. Neive attended session two with two family members, where her home life was described by her family as a disordered environment where there were frequent confrontations both within and external to the family home. Although Neive had completed the between-session task set in session one and was motivated to participate in the second session, Geoff noted she had some difficulty understanding certain BA concepts. She attended session three with a parent who reported her behaviour was worse at home, and that Neive "did not feel that the BA was working". Neive denied that there were any difficulties between her and Geoff (as the clinician wondered if his gender may have been a barrier) but she felt that her impending exams needed to be her focus. This suggests therapy must be offered at a time in young people's lives when they are willing and able to participate. For this reason, the family stated their preference that Neive received medication, as it was more convenient. The family were discharged after no further engagement. This highlights the often turbulent home lives of young people living in a socioeconomically deprived area and the realities of delivering therapy in this context. In fact, the experiences of individuals who discontinued treatment and the clinicians working with them raise the possibility that it may be naïve to think that BA treatment will be applicable to all young people. Rather, like the CAMHS clinicians reported in the focused ethnography, young people may not have the 'headspace' to commit to a talking treatment, such as BA, which required active participation.

Patient received three sessions of BA: treatment was stopped prematurely by clinician

Sharon (S5) ceased BA treatment for Frankie (P2) citing that she felt that the young person did not require further sessions of BA. According to Sharon's notes, Frankie engaged well with BA in session one, despite being "very verbose" and apparently distracted and directing attention towards matters not included in the manual. No difficulties were reported during session two, although Frankie had not completed the between-session task, which was discussed and re-administered. In session three, Frankie had not completed the re-administered between-session task. The clinician was pleased with the range of activities Frankie was currently engaging in and noted that the young person:

> "…fully realises it was their anxiety and fear of doing things that was making [them] feel unmotivated and is fully committed to engaging in more activities where [they] can"

Sharon went on to explain that both Frankie and their parent reported that Frankie's mood and difficulties with motivation had improved, so the clinician suggested terminating BA at this point, which the family agreed to. The reasons for the termination of treatment were explored at the interview with Frankie, who was somewhat unsure why their treatment had stopped but felt that it was their own decision to end treatment sessions.

> "I don't know, I just thought, like think, I just came to the conclusion myself that that's it, you know. Like there's only so much that therapy can do" [Frankie]

> "[Sharon] talked to us last time, didn't she, and said look she felt that you'd gone as far as you could, what did you think about it? And you kind of agreed didn't you? ... So three [sessions] seemed all right, and then you've got two sessions just to chat to [Sharon] haven't you this week and next" [Frankie's parent]

Frankie felt the sessions received had enabled them to arrive at a level of acceptance about their depression:

> "Like basically I've realised that depression and mental health issues kind of run in my family, and so chances are it's not just a slump thing, it's probably a lifelong thing that I'm going to have to deal with. And just letting it completely ruin my life is no way to go about it, so I've just got to figure out how to drive this thing along and learn to cope with it, and just try and function as well as possible and just not let it destroy us"

Frankie's quote above echoes some of the concerns raised by clinicians of parents bringing their own mental health concerns into treatment sessions but, in this case, the young person takes a more matter-of-fact approach. Frankie states that understanding their family problems has enabled them to move forward by gaining a level of acceptance with the status quo. Frankie describes the learning process undertaken and suggests that although they did not have the eight recommended sessions, they came away from treatment with further insight into their depression. However, it is important to note that Frankie reported they had been unable to complete all of their goals within the few sessions offered.

In both cases where treatment was started and terminated prematurely by the clinician, there was evidence that both therapists (Sharon S5 and Bridget S6) did not always deliver the BA as per protocol. Furthermore, the parent of another of Sharon's patients recounted how Sharon had not challenged their young person's (David P3) excuses for not using public transport during their between-session task:

> "There's no real motivation is there if there's nobody at the other end to meet you and do something. So it's still a work in progress isn't it, and [Sharon] was fine with it wasn't she when we kind of explained that was the issue"

In one other case, where the young person was not given the full complement of eight BA sessions (Victoria [P8] who did not respond to repeated requests to participate in the interview), the participant received seven sessions as prescribed by her practitioner.

Barriers/facilitators to treatment

In addition to the parental and treatment delivery barriers and facilitators identified above, young people and staff identified various issues that affected clinicians' or patient's ability to engage in or complete BA treatment. These obstacles fell loosely

into two different groupings; internal and external barriers (see Table 18 below). Internal barriers were often related to thoughts, feelings or abilities that restricted the young person's participation in treatment. External barriers were perceived to be outside of the young person's control and broadly related to obstacles that restricted them achieving their treatment goals. Some examples of these themes have been referenced in the discussion above, as they were relevant to the format and delivery of treatment. An overview of the internal and external overarching themes is discussed below, separated into each individual theme.

Table 18: Themes emerging from the qualitative interviews

Overarching Theme	Theme	**Description**
Internal barriers/facilitators	*Motivation*	Motivation could be a barrier or facilitator for BA treatment. One aspect was acceptance and/or acknowledgement of depression. This theme also incorporated young people's motivation to change their depressive status. Young people, their families and clinicians acknowledged that effort was required in order to make changes in their life.
	Comorbid Conditions / Individual Differences	Comorbidities or individual differences were a barrier to engagement in the intervention. Young people, their families and their clinicians reflected upon the impact these difficulties had upon their depression, treatment experience and the impact of the intervention.
	Memory/ Intelligence	Some young people and clinicians reported that poor memory or perceived intelligence was a barrier to successful treatment.
External barriers/facilitators	*Support Network*	The level of support available to young people whilst undergoing treatment was a barrier when friends or parents were unavailable to help young people achieve their treatment goals or when other's poor mental health impacted upon the young person's own mood. However, friends and family could also be a vital source of support.
	Resources	Barriers to young people achieving their

		treatment goals could be of a practical nature, such as a lack of financial autonomy or conceptual, such as a lack of freedom from parents.
	Environmental Impact	Environmental restraints, such as living in a rural location, presented a barrier to opportunities for activation. Other serendipitous events could act as a facilitator to young people's achievements during treatment.
	Treatment Specific Factors	Barriers and facilitators were also identified in the materials and/or content of the therapy. Also incorporated here are families' perceived therapeutic alliance with their clinician and therapist equipoise- the extent to which clinicians had belief or faith in the treatment they were providing. This theme includes beliefs about how BA would fit into staff's usual practice.

Internal barriers and facilitators

Internal barriers to BA treatment were perceived as being under the control of the individual, and were often difficult to tackle (see Figure 23). As identified by young people, their parents and clinicians, internal barriers included motivation, comorbidities or individual differences and difficulties with remembering or understanding the content of BA sessions.

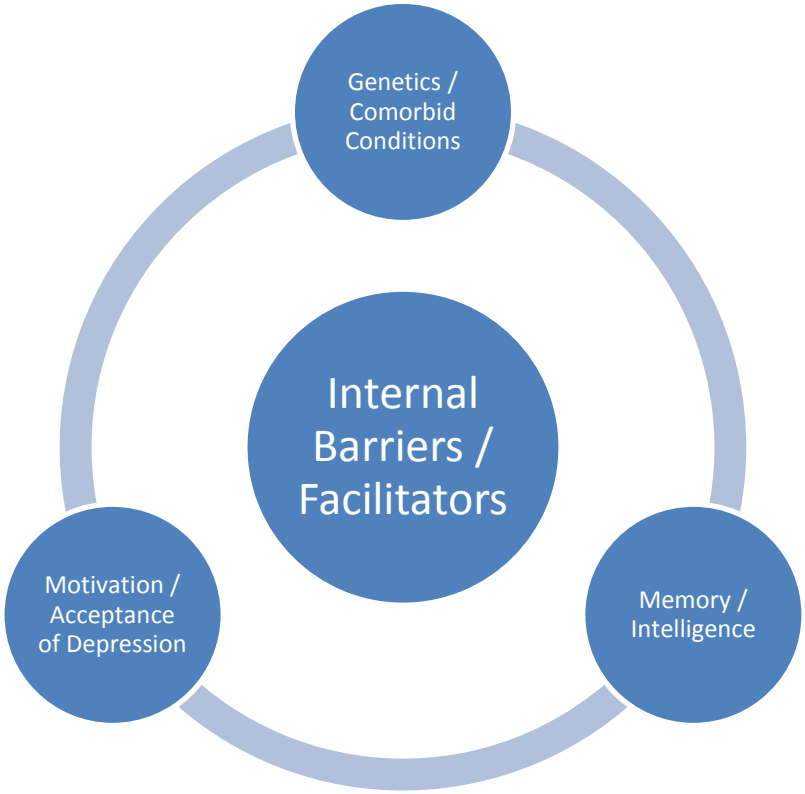


Figure 23: Pictorial representation of identified internal barriers to successful BA treatment by young people, their parents and clinicians

Motivation

For some young people, motivation to participate in BA treatment and/or to improve their depressive symptoms was a key barrier and/or facilitator in their treatment progress. Estelle (P5) struggled with low motivation, and initially found it difficult to complete the tasks set by Nicola (S2), despite valuing them as part of her BA treatment:

> "Not to do with the tasks, but more personally. Like if [the depression] was really bad and I just really couldn't have the motivation to do anything. But usually with [the BA] I would try and put that first, and even if I really felt like not doing anything I would still try. But overall [the scheduled tasks] were pretty good" [Estelle]

> "…motivation, I didn't have a lot of that, and I was pretty lazy and didn't like doing anything, I think that was, the fact that I had to suddenly put in quite a bit more effort than I would…" [Estelle]

She linked this poor motivation to her own individual traits, and it is striking that she spoke about these characteristics in the past tense. Her parent confirmed that despite these initial difficulties with motivating herself to actively participate in her BA treatment, Estelle had subsequently engaged well. The parent pointed out that the reason Estelle had succeeded during the treatment was a direct result of the effort she had put in. Estelle agreed with her parent's sentiment. Again, this is an occasion where the young person's subjective view of the situation did not initially tally with their caregiver's view of the situation. Or, indeed, their own view of themselves.

Staff members also clearly articulated how success in therapy was related to the impetus of each individual themselves. Shane (S3) said:

> "Involvement with particular aspects and particular tasks I think is predominantly down to the young person themselves"

> "It really depends on how engaged with the model the young person is. The first service user I saw [Alicia P11] as I mentioned was completely disengaged. Effectively she wanted to have a chat in our sessions, and was able to relate items back to the BA model but I think largely to appease me rather than as a therapeutic benefit for themselves... But that wasn't an instance of oh I didn't have time, I was too busy, or I didn't have time, I forgot; it was oh yeah I remember that sheet, but I just didn't think it was worth doing".

> "Filling out an activity sheet is actually really difficult unless you do it at the time. And getting that motivation for somebody who's got that high level of low mood is not always feasible"

Shane highlights it is not enough to attend treatment sessions and complete the tasks set, there must be a desire to improve their depressive symptoms. Geoff (S1) seconded the view that the success of treatment was dependent upon the young person's commitment and motivation to change. He found BA treatment worked well when the young person wanted to engage and move forward with treatment, such as in the case of Lucy (P6). Geoff was able to consider this against his experiences with less motivated young people, such as Connor (P9) and Neive (P10), who were much less engaged. This echoes the earlier views on parental involvement related to caregiver engagement in the goals of treatment. Lucy (P6) focused on her internal motivation to change and desire to improve her mood as a key treatment facilitator:

> "I attended all of [the sessions] on the right dates. And I think it was because I knew that I needed help with things, I wanted the help with it. But it had taken quite a bit of time, like two years to come to terms with I would need help with this and I can't do it by myself. And I think some people might miss [the opportunity] if they still can't accept that somebody can help them with it. And [depression] is something that can be not necessarily fixed but dealt with and controlled"

Lucy emphasises both the importance of being ready to make changes to her life, and an ability to gain a level of acceptance in relation to her depressive symptoms. In

this case, she found that although depression may not necessarily be able to be fully eliminated, it could be controlled. Lucy's experience illuminates the driving factors behind her motivation to engage with BA treatment. For other young people, it was harder to define their sources of motivation: it wasn't clear whether the motivation was internal, or whether it was the external support offered by their therapist that led to improvements in their mood. Jennifer (P1), for example, felt "under pressure" during treatment but was not able to identify from whom the pressure originated. Her parent felt this pressure was a positive thing and it was responsible for "pushing" Jennifer through treatment. Frankie's parent suggested that this internal barrier of motivation intertwined with the external barrier of *support networks,* as, without the support of external individuals, the young person may lose their own sense of motivation:

> "There's no real motivation is there if there's nobody at the other end to meet you and do something" [Frankie's parent]

Comorbid conditions/individual differences

As mentioned earlier, some staff and young people found the participant's comorbid conditions of anxiety, conduct disorder or ASD, influenced their experiences of BA. For some young people this meant they required a greater number of BA sessions in order to allow more time to focus on their comorbidity; for others, a one-to-one 'talking therapy' may not have been appropriate, or an alternative to BA treatment may have been necessary. In contrast, other young people who shared these comorbidities (of anxiety and ASD) did not identify them as a barrier to engaging with BA treatment. Similarly, young people identified individual differences, such as genetics, as a factor in treatment.

Linked to the theme of *motivation* described above, Frankie (P2) felt that some things were beyond an individual's control, such as inherited characteristics:

> "Like there is only so much that therapy can do…Like basically I've realised that depression and mental health issues kind of run in my family, and so chances are it's not just a slump thing, it's probably a lifelong thing that I'm going to have to deal with"

Frankie reflects that factors, such as genetics or family circumstances, cannot be changed, but do need to be acknowledged as Frankie felt they were fundamental to the development of Frankie's own depression and should be a consideration during treatment. Frankie valued that these aspects were able to be included in their own individual BA treatment formulation.

Comorbid conditions also interacted with treatment. One young person's diagnosis of an ASD meant they found it difficult to engage with various aspects of their therapy. David (P3) reflected:

> "Yeah. I found [BA] somewhat helpful, but I found it quite awkward, because I'm not used to being, I don't really like being in a room with just one person. I find it very hard to speak to people and it's, and when you're sort of just sitting there with somebody it's hard"

The one-to-one sessions were a social challenge for David, as were many of the activities proposed by his clinician Sharon (S5). David felt that he most likely had a different treatment experience to other young people his age, due to his ASD diagnosis. David's clinician, Sharon (S5) found that David's personality and ASD made it difficult for him to be flexible or open-minded to alternative activities (to his usual solitary interests) during therapy. Several staff members felt that such comorbid conditions presented a barrier to successful treatment:

> "I think the other difficulty I found is looking at comorbidities. I know as part of your study you included, it was any comorbidity was it? Any comorbidity providing the risk wasn't massively immediately severe. So

> one of the difficulties I found was comorbids, you know, neurodevelopmental disorders, I found working with a young person with an ASD, with Asperger's, it was particularly difficult because sometimes the internal barriers and external barriers all were very blurred. In that it's very, well it's very easy, throughout all of the psychoeducation that this service user had had from their diagnosis of Asperger's, they were very quick to say I want to be more socially active, I do approach groups of people, but I often get rejected from those groups of people because I'm socially awkward. I'm socially awkward because I have Asperger's. I've done skills training; they've told me sometimes people are going to reject me because I'm socially awkward. So in that aspect I think it often feels like there are elements of cognitive therapy that are needed within that. And I think with the work I did, the BA I did that was solely low mood and a bit of anxiety as well, BA was spot on perfect. It couldn't have worked better. But I think when you've got ASD and potentially ADHD as well, you do have to think about how you can integrate that with other therapies. And that might just be my psychological stance on it" [Shane S3]

> "It was difficult for my client to think of tasks he wanted to complete. And a lot of times he would say the same thing" [Sharon S5]

> "[H]e didn't have many interests. He only had very specific interests as he had ASD, and a lot of them were introspective introverted interests that didn't involve him getting out and about, which is really what he needed to do. So it was quite difficult" [Sharon S5]

Shane (S3) highlights how useful BA treatment was to improve low mood symptoms but suggested additional 'cognitive' elements may be required for young people with neurodevelopmental difficulties, such as those with an ASD. This echoes earlier sentiments from other clinicians. Sharon felt so strongly about this that she went on to suggest that BA may not be appropriate for complex young people such as David. Sharon reflected that BA may be more suitable for young people with less ingrained difficulties who are motivated to make changes to their routines:

> "I think if you have very simple cases or working with clients who are already coping quite well and are very motivated, it's kind of, it offers them a few more little tricks to put into their resiliencies, which will be quite useful. But I think for more complex clients that really need a relationship and proper understanding and empathy, I don't think it's very good"

This feedback may reflect Sharon's experience in the BUDDY study of dealing with two complex Tier 3 individuals (David P3 and Frankie P2), both of whom had an ASD diagnosis. David was not alone in finding that his comorbidity influenced his ability to engage in the BA treatment. Estelle (P5) found that her comorbid anxiety complicated treating her symptoms of low mood; she hypothesised that her underlying anxiety was responsible for feeding into her depression. As such, Estelle thought her treatment needed to focus upon her anxiety rather than her depression:

> "I notice that it's been easier to get out of my low mood and that. I normally only get it when I'm anxious, so I need to sort my anxiousness out and then I think lower mood will go"

The treatment of complex young people suffering multiple difficulties presents a challenge for individual, clinicians and services.

Memory / Intelligence

Some staff members questioned whether successful engagement in treatment might be dependent upon intellectual ability:

> "I don't know if this is about intellectual ability. I found [BA] worked really well with the young person who was intellectually very bright, less well with the one that wasn't, really" [Geoff S1]

> "I think were some difficulties, just thinking back about some other BA work I've seen, there were some difficulties around understanding the model. And I think from my experience of therapeutic models BA is one of the most simple, which I think is why it's really good for service users. But I think you kind of still need to rely on that cognitive level that a young person is able to understand. And not just that cognitive level, I suppose, but also that meta-cognitive level. If they can't be reflective about it then this is why this is happening, this is how I feel, they don't have the skills necessary to do that. In the same way as CBT you need to acknowledge that they can reflect on their own mood. If you can't do that then BA is not going to work" [Shane]

This was evidenced in the ability of young people to complete homework tasks that were set, indicating perhaps that a young person's ability or capacity, as well as

motivation to engage in treatment, is an important element in the subsequent success of therapy. In most cases where homework tasks were not completed, this was linked to difficulties remembering to complete the task.

Other staff members and young people suggested it may be difficulties in retaining the session content that caused problems. Two young people reported difficulties remembering the content of sessions or recalling the details of their assigned between-session tasks, such as completing a mood diary. Jennifer's parent (P1) felt this was due to their child not reading the materials that were provided. Frankie (P2) found it hard to remember to complete the tasks:

> "I feel like maybe that mood diary thing that she wanted me to do might have been helpful if I'd actually done it, but I kept forgetting"

The young person's carer challenged this by pointing out that, since treatment finished, Frankie had bought and completed a regular mood diary. The parent thought the mood diary was a good idea as it allowed the young person to revisit past events and this was viewed as an important tool for Frankie to maintain a positive mood. A staff member found memory was also a challenge for another client:

> "We were finding session by session they could rarely remember any of the BA that we'd gone through using the manual; however, yeah they'd activated really well. They weren't doing any of the between-session tasks. So what we ended up doing in sessions was almost abandoning the manual…. and just referenced the activation that this service user was doing in the context of their BA formulation and thinking about it more, I suppose more as a process than as an individual instance of something that they'd done. And I think that's probably the thing that's going to help in the long-term with that service user [Alicia]". [Shane]

The clinician did not attribute this activation to the BA treatment, rather to 'extra therapeutic factors' such as concurrent efforts to return to education. Such serendipitous events will be considered as a facilitator under external barriers.

External barriers or facilitators

External barriers were generally outside of the control of the young person and were often of a practical nature (see Figure 24). They related to the support network surrounding the young person, environmental events or resource limitations that may influence treatment and factors specific to the BA treatment. For parents, their own mental health represented a barrier to offering support during treatment and for clinicians, their lack of faith in the BA treatment acted as a barrier to delivery of the treatment.

One staff member reflected how there may be insurmountable barriers during the course of BA treatment, and questioned whether this was adequately addressed in the manual:

> "I think one of the biggest problems I found with [BA] is the dependency on the ability to overcome barriers. And I think like all behavioural and cognitive behavioural interventions, it's very heavily designed around overcoming internal barriers, navigating around external barriers. Throughout the training that we've had and throughout my experience delivering it, we've had very little guidance on when external barriers are not 'overcomeable' – if that's a word" [Shane S3]

Shane went on to discuss how many young people may face recurrent "physical, real [or] concrete barriers", separate to BA, that are also unfeasible to overcome. He felt that BA was perhaps not able sufficiently to address such situations.

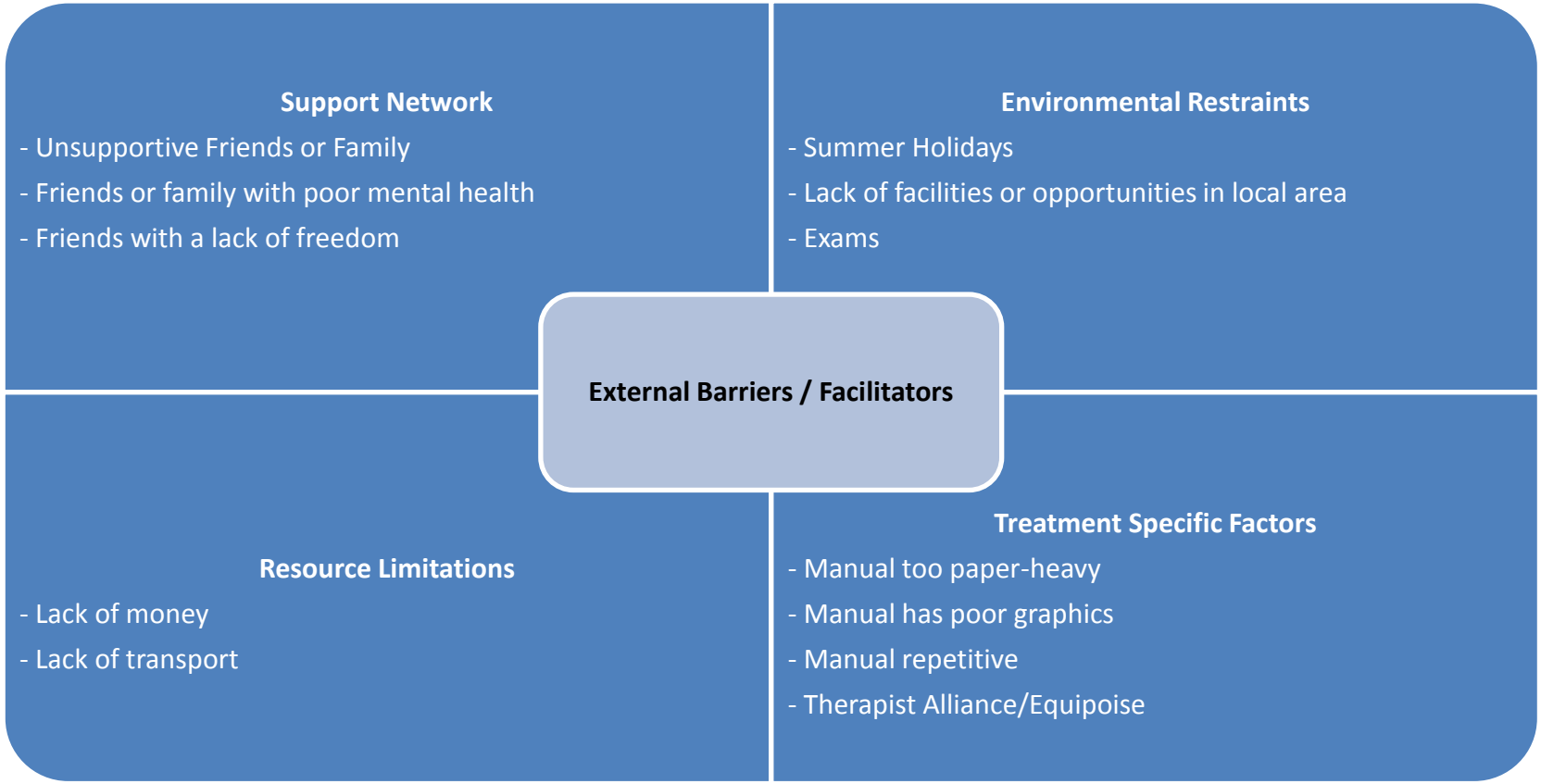


Figure 24: Pictorial representation of identified external barriers to successful BA treatment by young people, their parents and clinicians

Support Network

As alluded to in previous sections, the external environment that young people live in acts as a facilitator or barrier during BA treatment. One aspect of this is the social support network of friends and family that they have around them. For David (P3), his desire for no parental involvement in his treatment was at odds with his parent and clinician who both believed increased parental involvement would have resulted in improved treatment outcomes. When the reasons for his parent's lack of attendance were explored, David's parent reported they had their own internal challenges to overcome and cited these as a reason for not attending David's (P3) treatment sessions:

> "I'm going to admit it…I was going to go towards the end but, and I'm going to say this and it's really stupid and you'll think I'm ridiculous, but where the place is situated it's opposite the police station. And my husband, soon to be ex-husband and his girlfriend work there, and I lost my nerve of going" [David's parent]

Again, this is indicative of parental issues being revealed as a barrier to attendance at their child's therapy sessions. This is analogous to the reports of parents bringing their own issues into therapy sessions.

Frankie (P2), who received three sessions of BA, identified that their external environment was making it difficult to complete the tasks and goals that had been set by their therapist Sharon (S5):

> "She [Sharon] had a few goals that I still need to try and sort out, like taking the bus by myself, going out more. But the problem is all of my friends are really introverted and depressed and indoorsy and I hate them. I really want to fix this whole slump I've forced myself into for the past three years and, like, none of my other friends give a shit. They all just want to rot there and, like, die"

Frankie's friends were not a positive source of support. Sharon identified that a young person's friendship group also had an impact on David, another of her clients:

> "If he [David] actually had more friends, that might have helped. If he'd had interests in this country that might have helped." [Sharon S5]

Sharon refers to David's only hobby, a niche international interest that was not easily accessible in the UK. Patient Frankie also reflected upon how external stimuli such as their friend's poor mental health, had impacted upon their own mood.

> "Oh yeah, [my friend], his mum found out that he'd been self-harming and she wouldn't let him leave the house alone. So I couldn't hang out with him at all. And he's not in my college anymore so I don't really see him now. So I just talk to him on Facebook. And [another friend], she has, she's got something. Like, despite being in therapy for the majority of her life she's never had it officially diagnosed, and that's really fucked up I think. But she shows quite a lot of signs of some kind of autism and various other things. But like her parents are really weird with it. She even claims that they're not overprotective but I know that they are – like it's really just easy to spot" [Frankie]

Frankie's parent agreed "There wasn't really friends available either. I think that was the big thing wasn't it?" These quotes highlight the impact of significant others in young people's lives which is an issue that is very difficult for therapy and therapists to address: however, it should be noted that, there may be a link back to the *comorbid conditions/individual differences* theme, as both Frankie and David suffered from an ASD, which is linked to social difficulties.

As discussed earlier, other young people and staff members felt parents were a vital source of a support. Shane reflected on whether parental involvement was a hindrance or facilitator in the context of BA treatment:

> "I think if parents are quite encouraging that can be a good thing. But I think parents can be over-encouraging, particularly when it's around activity diaries, mood diaries that can be quite personal for the young person. Do I think this behaviour was helpful, did it lift my mood? So I think parents have a beneficial effect"

Environmental Restraints

External events and the physical environment in which young people live impacts upon the success of BA treatment. Frankie continued discussing the impact of outside influences in relation to their BA treatment by detailing the lack of places to visit in their local area and restrictions due to their friend's preferences. These outside influences had an impact on completing between-session tasks:

> "But the problem is there's nowhere really for us to go other than [nearest city], and I'm only really friends with people at my college now who are all from [local town] so they don't really give a shit about [the city]. I do have this one friend …but he never wants to go to [the city], because he goes to [the city] all the time basically. And whenever I want to go suddenly it's too much of a hassle for him. I think he is feeling depressed lately but he's like just not, he's just like completely repressing his feelings and not talking to his parents about it. And he's like gone off his therapy counsels and that, and I'm like you are, that's a really bad idea"

Again, echoing the impact of the support network theme on young people's lives and opportunities.

A staff member similarly felt that where the young person lives could represent a barrier to their successful engagement in treatment:

> "And sometimes being able to say well what is it you'd get out of doing this, can we find another way into it, is not feasible. For example if the service user has no means, if they live in the middle of nowhere, which a lot of people in [the area] do, and they've got no means of getting out of the house into a social hub, if their goal is to be more socially active and if they're feeling low because they're socially isolated, there may not be a way to overcome that" [Shane]

Shane particularly comments on how this environmental restraint limits the opportunities for coming into contact with differing sources of positive reinforcement (i.e. hobbies, friends). This is a key aspect of 'activation' during BA treatment.

Resource Limitations

David (P3) found a lack of money hampered completion of certain activation tasks, such as days out:

> "Money, travel, I can't really travel to many places because you have to get a bus…because I like going to museums and art galleries, [but] there's not many in reach of buses and it takes too long to get there"

David's parent found this particularly frustrating, stating, "Well, you see, if you'd asked me I would have given you some money – I didn't know that", again highlighting a potential benefit of parental participation in treatment. Of course, on the contrary, it could represent an excuse on David's part, as to why he could not complete his between session task. This would link back to the internal barrier of *motivation*. David's parent felt that the summer holidays had disadvantaged progress in treatment "…and of course it's the summer holidays so he doesn't have to go to wherever, you know". This is in line with the effect of his therapist Sharon also taking time off during the summer months.

Treatment Specific Limitations

Treatment Manual

Staff identified the manual materials may have hampered delivery of the BA model. Paul (S4) suggested moving the concept of goal-setting to earlier in the course of treatment. Paul found the manual itself was too paper-heavy, required slimming down so that it was not overwhelming to the clinician, and that the graphics could be improved for the young people (i.e. it was perceived to be "a little bit clipart heavy"). Although, interestingly, the graphics were not mentioned by other young interviewees in this current study. Geoff (S1) seconded this sentiment related to the manual graphics, but also commented that the prescriptive format of the manual

aided the continuity and management of the therapy delivery, helping the clinician keep up with where they were with the work. Nicola (S2) felt:

> "…the layout of it is fine. A bit cluttered I found. The ones [worksheets] that stand out are the ones that make visually more sense"
>
> "…one of the packs was very long"
>
> "…some of it was too wordy"
>
> "[Some worksheets were too] busy for me. If they had more space, just a bit busy maybe"

Nicola reported young people did not like the homework, "but the ones that do it, again that's motivation to do that, they really didn't like. She [Estelle P5] wasn't too bad actually but in general they're not fond of homework, so you're only as good as the homework you do". Sharon (S5) felt that that there was a lot she did not like "a lot of it that would have trimmed down and just put into my ordinary way of therapy, which would be counselling/psychotherapy. I thought it was repetitive. I understand why they want it to be repetitive in some way but I still thought it was repetitive". Like Paul, Sharon felt the materials were helpful but "initially a little bit clunky". In particular she felt young people struggled with the activity sheets and identifying how they felt at a particular time, as it proved too complicated for them due to their other commitments and finding the time to record this information. It was suggested an electronic format may be a better way to record this information, such as a phone app.

Therapist Alliance

Shane (S3) suggested the biggest barrier to successful BA treatment was poor therapeutic alliance between therapist and client:

> "I think the biggest barrier for service user engagement in BA, in any therapy, in any intervention, in any service, is that therapeutic alliance,

> and I think young people need to be listened to, and I think they need it acknowledged that they're being listened to. One of the advantages I had was that the service user I was working with identified me as not being one of those old therapists. Which put us more, I suppose more comfortable around each other, and that instant rapport building was much easier. So I think one of the barriers is just how well you get on with your therapist. And I think the other difficulty with this [BA] intervention, of course, is thinking about collaborative care and shared decision-making. We actively promote [as a service], if a service user doesn't feel that they get on with their therapist they tell someone and they get a new one. Now if you're midway through a manual that's not going to be practical on the therapist or on the service user. Well, a new therapist or the service user, that is. I suppose that's the main engagement with the model is around that therapeutic alliance" [Shane]

He proposed this wasn't specific to BA, but to any psychotherapy delivered through CAMHS.

The therapeutic relationship between the young person and their therapist was highlighted as a facilitator by a parent who described their young person's (Frankie P2) positive experience "I just think talking to [Sharon S5] really, and having her saying why don't you try this or you're doing really well…You know, I think somebody else telling you that you're doing well is a good thing, isn't it?".

> "Well I think it's effective and it helped us" [Frankie]

> "I think it's helped a lot. The lady that I did it with was really nice, and she gave me goals. And I think they were good because I actually tried to do them and stuff. And then she gave me sheets of paper that you had to write down what you did, and I found them good because I felt as if I could write what was happening and what my triggers were" [Estelle P5]

It was the goal-setting that Estelle felt made the biggest difference. Both Estelle and her carer identified having a clinician (Nicola S2) that they liked impacted upon their treatment experience; "We've enjoyed it. Got to know the clinician, didn't we, and she was really nice". Estelle said that "she listened", and that "it was nice to have

help". Her parent said, "…they've got to show empathy haven't they, and she did". In return, their clinician Nicola recalled that:

> "On the surface the girl was very much a people pleaser, very much. But I could tell that the biggest barrier again was avoidance. So the avoidance, there were a couple of times where she was teary and defensive. But when we went for the final session she admitted that defensiveness was part and parcel of it all, and she overcame them. So you're not going to nicely overcome your fears. So I'd say it was very understandable, run of the mill relationship between the person doing the treatment, the therapeutic relationship was as expected and avoidance is part and parcel, you know, there's no magic wand"

Lucy (P6) valued the comfortable relationship with her therapist Geoff (S1), assessing it as helpful; "Yeah I think so. I think if it was someone that I didn't, not necessarily see eye to eye with, but someone that didn't fully understand or listen to what it was, or assumed it was to do with something when it hadn't been fully explained". Lucy's parent said "I think you felt quite comfortable didn't you, talking to [Geoff]…He was very good". In turn, Geoff felt the therapeutic relationship between patient and clinician had been strengthened by the weekly format of sessions making it "much more positive, much more engaged", even in cases where treatment was viewed to be less successful. In the same way that young people felt the staff member they had been assigned impacted upon their treatment experience, staff felt that the young person they were allocated also impacted upon the success of the subsequent treatment delivery. When reflecting upon a "less successful" experience of delivering BA, Geoff felt "I think that was about the profile of the young person in lots of ways". He also attributed a successful case (Lucy) to the intrinsic abilities of the young person;

> "[Q]uite articulate, a high achiever at school, very much quite precise in terms of what she did and how she approached work. So a BA model suited her great. It really fitted well with her" [Geoff]

David (P3) felt that his therapeutic relationship with Sharon did not make a difference to his treatment. However, therapist Sharon though that "it might be difficult for him because of his ASD, because of his diagnosis. And, I mean, I do think that the most important part of therapy is the relationship, which is acknowledged as the most important part in most circles, and BA isn't really about the relationship".

Therapist Equipoise

Some clinicians did not value BA in the same way as other therapies, such as CBT. One clinician, Sharon (S5), stated she did not like the therapy and would not chose to use it as a stand-alone treatment. However, she did concede that she found the component BA parts useful and would deliver them alongside other approaches. Understanding why this might be the case is vitally important, as without clinical equipoise, it would be inadvisable to attempt to implement the treatment in practice. Shane reported that he held a lack of faith that the BA treatment would help Alicia in the long-term. Instead, Shane chose to rely upon his own clinical judgement in relation to the aspects of the BA treatment he felt would be most helpful to improve Alicia's symptoms. These adaptions were not in-keeping with the suggested model of delivery and would require further monitoring and exploration in a future trial. Similarly, Nicola (S2) reported:

> "I had a very amenable young person [Estelle] and I think that made a big difference. Well she was amenable on the surface… underneath she was very resistant"

> "[The family were] a very straightforward family to work with on the surface. The difficulties the girl [Estelle] faced were very ingrained though I think for BA"

Again, this implies a lack of confidence that the BA treatment would suitably address this young person's symptoms, suggesting there may not be therapist equipoise. Staff felt there were limitations to a BA approach for depression:

> "I think behavioural activation, I just think it's got those clear limitations around sometimes you do need to go further" [Shane S3]
>
> "I didn't feel that I could address in this type of therapy what I wanted to address" [Sharon S5]
>
> "I find that using, having to use pure BA I feel very constrained and it hampers me. It hampers my intuitiveness and my kind of natural, the natural flow of therapy. And I don't like it" [Sharon S5]

For Sharon (S5), it was her own internal challenges that were most difficult to overcome, in order to deliver the treatment.

Sharon (S5) also felt the BA approach was particularly suited to "practitioners who are very logical and like to follow procedures without having to think a lot for themselves". This contrasted with feedback from other members of staff, who felt the approach suited them and some of the young people they were delivering treatment to. Nicola (S2) went on to report how her confidence in delivering therapy meant she did not struggle with delivery; "I think in general I quite like chatting to people anyway so for me just part and parcel. Because it's your confidence in yourself isn't it, so I didn't struggle with delivery". In contrast, Sharon (S5) felt the prescriptive manual and the acronyms were unhelpful; "Well, as I say, I felt constrained and I felt limited and I kept having to interrupt my train of thought to look at what various abbreviations meant and things. I felt that I wasn't really listening to the client; I was more thinking about what I was supposed to do next in a procedural way". Nicola agreed and felt some acronyms, such as TRAP and TRAC, were not easy to get across to young people, even if the theory behind them was

good. In contrast, other clinicians, such as Paul (S4), felt a BA manualised approach (with worksheets) sat well with his previous background delivering youth work interventions. He reflected on the fact that he had not been trained in any other therapeutic interventions. As discussed in the earlier ethnography (Chapter 3), this would again suggest that there cannot be a "one size fits all" approach to training or to staff recruitment to trials in this setting, and that such contextual factors need to be carefully considered.

Helpful and unhelpful aspects of treatment

Multifaceted change was reported for most of the young people interviewed and this varied from small one-off instances to large sustained improvements. Progress reported by young people was not necessarily related to aspects of their life targeted for 'measurement' using quantitative outcome measures. Instead, young people spoke about how their motivation had improved rather than concepts such as self-esteem or specific depressive symptomology. In general, staff reported that the content was understandable and acceptable to the young people they delivered it to. Most staff also reported liking the treatment and found it useful to improve symptoms of depression. There were, however, some caveats.

Estelle (P5) found that BA treatment "definitely helped with my low mood" and particularly liked the goal-setting elements of treatment. This was in contrast to her therapist, Nicola (S2) who felt that young people did not enjoy the between-session tasks, although she acknowledged that this may be a gendered issue, as some participating girls did like the between-session tasks. This was seconded by Frankie, who found that they were nowhere near as reluctant to go out following treatment as they had been previously.

Most staff and young people highlighted the goal-setting as a key part of treatment, and valued the progress made throughout this process of breaking larger tasks into smaller ones. Staff found that they were able to report improvements in young people, particularly in relation to achieving the goals they had set:

> "So the BA in fact for her was very good. It got her to do things, eat sandwiches in front of people [a goal]. It sounds really minor but if you're eating in the dinnertime you're probably feeling better later on in the day. Your physical and your mental health is very important, if you're not eating you are worried later aren't you?" [Nicola S2]

As previously mentioned some staff felt it was not in fact the treatment that was responsible for the reported improvements, rather it was external serendipitous factors:

> "Avoidance was the big thing. And because of generalised anxiety she actually believed in the reasons she avoided things. She really did struggle with [using] the bus. And it didn't matter how you unpicked it, as I said there was a bit of serendipity, she did do it. Whether that's got her back on the bus or not is another matter" [Nicola S2]

Despite Sharon previously expressing her dislike for the treatment approach, she concluded:

> "I think BA is a good little eclectic technique, but I don't really think it's effective on its own unless it's a very simple client that already has lots of resiliencies and resources"

This raises questions relating to the impact of how a clinician's belief in the efficacy of an intervention could impact upon its application in clinical services.

The actual contents of the BA manual and BA model were felt to be important by families and staff. While the manual materials were highlighted as an external barrier earlier, the manualised format was viewed by some participants as a facilitator. Estelle (P5) felt that she learnt "the right things I needed to learn" during her BA sessions. She went on to say "I liked the homework; it didn't really bother

me" and her parent confirmed she always completed the tasks she was set by the therapist. Shane (S3) described the success of between-session tasks: "I found the between-session tasks weren't very accessible for [Alicia] … The other service user I'm seeing at the moment [outside of the study], is massively engaged with it. Is doing every between-session task, is feeding them back, is reflecting on them before feeding back". When another young person was asked what happened during their BA sessions, Frankie (P2) responded "Basically I'd whine for a few minutes about shit, and then the lady would just actually tell us some good ideas as to how, I like, sort stuff out. And that's it". The practical nature of the treatment was a facilitator noted by some young people and staff delivering it. Lucy described how "it started with, it followed the booklet pretty precisely, because obviously it's a test, and it was pretty good talking about things and having the sheets to go back and work on myself. So it wasn't just someone talking and telling me what I could do, it was putting it into practice as well". They went on to say "I think the most important parts was not just talking about it and what I could do, it's making me put it into practice with the worksheets, and not with anybody else, like, by myself, so I could do it.".

Aspects of delivery

Staff were motivated and engaged in the study. Geoff (S1) felt that the "action orientated" part of the programme was the most beneficial part. Another member of staff (Paul S4) felt BA "…seems to make sense. The whole approach is something I feel young people can grasp rather than some kind of detailed knowledge of psychology or their brain. You know, it's how they're living their life which is causing low mood". Neither Paul nor Geoff could think of any parts of the BA concept that

they didn't like. Nicola (S2) thought some of the handouts were "fantastic" and particularly liked the ones on:

> "Mood directed behaviour, goal directed behaviour. I think that absolutely is fantastic. And they really get that, because you can't explain why you have to do things, not because you want to but because you have to, and it really nails avoidance really well- because avoidance is very powerful with depression and anxiety, so that made a lot of sense. I think once we'd done that it just slips into the language quite easily and yeah that made a lot of difference"

Sharon went on to say "I liked the first, I definitely liked the first session. I thought that was brilliant"; and the relapse prevention at the end of treatment because it was helpful to review how far Estelle (P5) had come during treatment. Nicola felt the key thing was:

> "the motivation at the start of BA is far more, it's not the BA package or anything, it's how motivated the family are to change. And for me that's the outcome of therapy, that's my strongest feeling about it, and that's one thing BA has really nailed home to me, I think, the family have to be motivated to change, not just the child. And there's no point in family being motivated to change if the child is a bit ambivalent, but they're very young"

This echoes Geoff's (S1) earlier observations. Although Sharon (S5) did not like the BA treatment as a whole, she did like some aspects of the BA model:

> "So what I liked about it is the model of what has led to somebody feeling the way they did and what maintains them in that state. I thought that was a good little explanation that could give someone kind of, oh what am I trying to say, a reason why they're feeling the way they're feeling. And I thought that was quite interesting and the clients found it quite interesting. I mean I know a lot of models can use their own way to explain behaviour, but as a model that bit was ok"

Sharon said "The other thing I did like, because I liked bits of it, I liked kind of the diary bit, although I wouldn't have made it as long. And the goal-setting, but I wouldn't have made it as long and done it in that format". David (P3) found BA treatment "quite easy to follow", with the most useful part of treatment being

"doing the things you'd talk about doing" such as the between-session tasks. These tasks comprised of David cooking more meals for himself, for example. Sharon, David's therapist reported his attendance was excellent and "he did complete the tasks that were set. Like he arranged and met a friend and went to [a shopping centre]. You know, he seemed to complete what was set". However, a conversation between parent and child illustrated that the family had reservations about whether the positive benefits would continue now that treatment had stopped.

Lucy (P6) found the start of therapy particularly difficult because they found it hard to explain how they felt. "I think the start was the most difficult bit, like, just understanding…with not really understanding how I felt in the first place". They felt that "at first it was a little weird, because I didn't really know anything about it. But after a while it was helpful". Their parent commented "I think it was good, because I could tell [Lucy] understood what was going on and why they were trying to do it that way. And she realised that it would be helpful". Lucy particularly liked that the fact that it was about her and focuses upon what she could do personally rather than being about what other people around her could do.

Staff indicated practice and familiarity with materials improved after their initial patient. Furthermore, supervision was seen by two members of staff (Paul and Geoff) as a facilitator for staying on track when difficulties were encountered. Geoff described how they had encountered problems with delivering treatment according to the manual and so had accessed supervision, during which they were advised to be more flexible and to treat the manual materials as a reference point. This "freed" them to not "tie yourself up with the paperwork". It appeared useful if the BA approach appealed to practitioners like Nicola, Shane and Paul "I really enjoyed it. It

made a lot of sense to me". Nicola said "I use aspects of it all the time. The whole ethos of it I used a lot". Geoff agreed "So I think that certainly from my positive experience it is a model that can be applied to clinical practice and it does have a good outcome". He went on to say "I think my view is that it felt satisfying in terms of my own clinical practice. I felt more in control. I felt that it had more of a structure. I felt more confident and competent in terms of what I was doing. So actually delivering it felt good, worthwhile". Shane said "my experience of the BA model was I suppose positive from a clinician point of view". He went on to say "Personally I found the model really engaging and really positive. I think it's got a lot of really good things about it. And I think, yeah, being able to demonstrate how the model applies is really good; however, I think the manuals that we ended up using have far too much information. For the session constraints we have, you would need a massively engaged positive service user, and realistically if you've got a massively engaged positive service user, they're (a) not going to have low mood or (b) they're going to last eight weeks before they're ready for discharge".

> "It's a tricky one. I'm very hesitant to comment on the effectiveness of an intervention without first seeing an evidence base. And I know the evidence base for BA is currently not great, particularly in children. However I think as a model, and this might just be me being a lazy therapist, I think it's a very simple model which I think makes it very appealing to therapists, and also very appealing to service users. And if they can fit themselves into that, I think they get on really well with it. One of the other things that I've really liked about it is the very immediate nature of it, in a sense. So, service users that present with massive complex previous trauma, previous negative experience, if they don't want to focus on that, they don't need to. And I think that's really good. You can say yes you've had all this, it's horrible, I'm not going to dredge it up if you don't want to, what we're going to do is we're going to be able to talk through what the situation is now and how we're going to change that. That fits in really well with my ethos of that kind of mindful approach, which is why I think BA needs more mindfulness integrated, but that's a different story. What I'd like to see is I'd like to

> see how well it works alongside other interventions. Well, I'm just thinking when you've got people who have had massive histories of trauma, of abuse, it would be really interesting to see how well BA works for the short term where psychodynamic or EMDR interventions work for that long term. I've got no understanding of how they'd integrate. Currently I'm doing some work integrating BA alongside some systemic family work, which is quite interesting really because it almost bridges that gap between what are the barriers, how do we think we can address them, take them to the systemic session, talk it through with the family, and I find that's really useful. So yeah, I think it's really interesting to see how the cognitive component from CBT isn't massively missed, but I think it would be very naïve of us to say even with an evidence base, if that cognitive component is not there and we're getting positive results, that we couldn't improve upon those results with additional integrated therapies " [Shane S3]

Finally, four young people and their parents couldn't identify anything unhelpful about treatment, with David stating that "… it was just, I can't really think of anything bad to say, it was just sort of all right".

Mechanisms of change

Geoff (S1) commented that it had been around six months since the first contact with the young people they had treated. He felt that the young person who engaged with BA (Lucy P6), where there was evidence of an impact upon behaviour and beliefs, had not regressed. In contrast, the young people who did not engage well (Connor P9 and Neive P10) and for whom there was less evidence of impact, have been re-referred to CAMHS for further input in terms of their care. The reason articulated for this, and the point that Geoff considered the most important in terms of patient care, was that:

> "…young people get engaged with things which help their mood improve, rather than them having to try and think of it in a different way, in terms of changing [your] thoughts before you change [your] actions"

Nicola (S2) reported that since the end of her BA sessions, Estelle (P5) had returned to CAMHS for treatment for her generalised anxiety. Nicola reflected that in this case

she felt Estelle's low mood was a symptom of her anxiety rather than vice versa and that BA may be best suited to "separation anxiety, low mood and some low level anxieties…And I very much think for school refusal it's brilliant. Anything to do with getting up and doing something, and having the tools to know that depression and anxiety is not just the way you feel, it's what you do, how you think".

Summary of BUDDY trial qualitative results

The feedback from both staff and participants overwhelmingly supports the weekly mode of delivery. Young people were generally found the length of treatment sessions acceptable .One young person would have preferred longer sessions, but he only received sessions that were on average half the maximum allocated length. Staff felt there was too much information to cover within the one-hour session length and also within the eight session limit. This led to difficulties delivering the manual content as intended. Although it is likely that young people were unaware of the content, staff were unable to deliver within the time/session restrictions. There was a mixed response in terms of the ideal number of treatment sessions; generally, participants felt the amount was sufficient to treat depressive symptoms, but some staff and families were concerned that the treatment did not address comorbid anxiety symptoms. Greater flexibility in the number of treatment sessions may address staff and family concerns that comorbid anxiety could not be addressed, and enable additional time to cover manual content. However, this needs to be considered in the context of the described service pressures.

Most families enjoyed BA treatment, perceived it as acceptable and noted improvements to their low mood as a result of treatment. However young people

and their families noted significant barriers to many aspects of BA that should be explored further. The feedback from clinicians was more mixed; few practitioners reported great problems delivering the treatment, but they did raise a number of important feasibility questions in relation to the delivery of the treatment and its utility.

Stage II Discussion and Conclusions

The BUDDY feasibility study is the first UK-based randomised trial in secondary care, of BA for young people with depression. This gap in the research was identified by the scoping review conducted in Chapter 1 and a recent systematic review of BA interventions for young people with depression (Tindall et al., 2017). This feasibility study shows that the BA intervention was potentially suitable to be disseminated and delivered in Child and Adolescent Mental Health Services (CAMHS) via the CYP IAPT service transformation initiative. This thesis brings together findings from the qualitative and quantitative outcomes relating to the BA intervention, across a broad range of domains. Primary findings relate to the acceptability of the BA intervention and the feasibility of the trial design in this context, which will be discussed below.

Recruitment

Staff

It was important that CAMHS sites were willing to participate in the research study and that they could also be retained throughout the trial. In this respect, the BUDDY study was a success; all the services that were asked, agreed to take part and continued participation until the end of the study. It was equally important that staff members from each site were willing (and enabled) to be trained in and to deliver the BA intervention. We found a small number of staff were unwilling to attend the study training due to other commitments, such as *CYP IAPT* training or their workload. Despite this, we were able to train the desired number of staff for the trial. There were no instances reported where the CAMHS service would not allow staff to attend the training, which is unsurprising due to the study sites being self-

selected. Furthermore, the findings of the Stage I ethnography meant that the training was designed to fit around the demands of the service by being delivered in two parts over two different weeks. This appeared to be broadly successful as the vast majority of those provided with information agreed to be considered (for training in the intervention), and most of those invited, attended.

One challenge of this recruitment approach is selection bias. Staff volunteered personally to be put forward for the training. More motivated staff may have been more likely to volunteer, whilst those unwilling to try new approaches or to take on additional work may not. This situation may overinflate treatment effect. This could present difficulties if the intervention were to be implemented into clinical practice as staff may not be representative of the CAMHS team as a whole. This feasibility study also demonstrated that most of those trained continued to participate in the study until completion. Those who were trained in BA but did not provide treatment during the study period remained motivated to participate but were restricted by various external barriers, such as changes to their job roles or no suitable young people being recruited at their site. Training for the BUDDY study was delivered across three days plus supervision; other applications of BA have used even shorter durations of training, for example one (McCauley et al., 2016) or two days (Weersing et al., 2008). Staff recruitment and retention exceeded the expectations formulated in Stage I of the research and proved to be feasible in this context.

Participants

Another central objective of the feasibility study was to assess the most acceptable, feasible and effective ways to approach patients to participate. Three different

approaches to this were explored. Both clinician-led and patient-led recruitment approaches were deemed acceptable to young people and their parents/carers. In line with previous reports from CAMHS services in the County Durham area (Affleck and Seed, 2015), we found that approaches where there had been prior contact (i.e. with a clinician) were the most successful. The case note review was time-consuming, unsuccessful (yielding few provisionally eligible patients) and ultimately unfeasible. The poster-approach involved minimum resources and although it did not yield large numbers of eligible participants, it proved the most reliable at identifying young people who met the provisional inclusion criteria. Conversely, due to the low numbers who contacted the study team after viewing the poster, it may be that it was unappealing to young people and/or their families. The clinician-led approach required more resources to implement than the poster (and less than the case note review) but provided a good recruitment rate and accounted for the recruitment of most subsequent participants. The high rate of suitable young people identified by their clinicians suggests that despite a lack of confidence initially, CAMHS staff understood and were able to apply the eligibility criteria effectively in order to screen patients. This indicates that the study information was appropriate, effective and was suitably disseminated around the CAMHS team. In a future study, it may be possible for clinicians to screen their own caseloads for eligible patients to boost study recruitment where necessary. The success of the poster and clinician based approaches suggest that a dual self- and clinician-led recruitment procedure would be the best choice for a future trial.

Rather than the mode of the initial approach for recruitment, it was the subsequent interactions that patients and their families chose to focus upon in

interview, commenting on the speed or content of the way they were approached. Although one family expressed dissatisfaction with the study name, the young person (David) themselves questioned whether their diagnosis of Autism Spectrum Disorder (ASD) meant that they offered a unique viewpoint to the study materials. It should be noted that another young person in the study (Frankie) also had the same comorbidity and did not comment that they found the study name to be unsuitable. Whilst one family expressed dissatisfaction about the way they were approached, the lack of other comments or criticism relating to the recruitment study materials would suggest that the PPI input prior to the start of the trial was effective, which is in line with previous research (Mawn et al., 2016).

Interestingly, at various points during the recruitment phase CAMHS clinicians excluded participants from the study for various reasons. Allowing clinicians the opportunity to assess patient eligibility for the trial in this way introduces another source of potential bias (selection bias), as staff's beliefs - for example, those surrounding the utility of the BA treatment - may have led them to exclude participants with a particular profile, yielding the sample unrepresentative of the study population to which the results would be applied. This would need to be explored, and potentially addressed if the same procedure were to be used in a larger study. As an alternative procedure, if researchers took on this role, robust risk management procedures would need to be put in place and it raises difficult ethical dilemmas relating to the shift in clinical decision-making from clinicians to researchers.

Poor recruitment is a common reason for unsuccessful trials (Lancaster et al., 2004). Although the recruitment period went beyond the intended 12 months, this

was mainly due to service restructuring, which led to increased internal waiting lists in CAMHS throughout the duration of the study, rather than difficulties in identifying appropriate patients. During the study there were a high number of patients screened but this converted into a low inclusion rate for both those provisionally and subsequently eligible for the study. The overall recruitment rate of 18% in the BUDDY study was much lower than that reported in large psychotherapy trials in similar populations where the reported rates were between 27-40% (Goodyer et al., 2017). If the BUDDY study had not used the case note review, and instead relied upon clinician and poster recruitment alone, the recruitment rate could be vastly improved (without impacting upon the numbers of young people identified) to approximately 67%. Greater resources (i.e. a research assistant onsite) to screen young people more quickly would improve researcher responsiveness, by recruiting more young people before their first treatment session. Extra resources would mean young people could be contacted earlier (reducing the time lag between contact and action) and this would mean patients would be less likely to have received a treatment session. More flexible inclusion criteria would also enable inclusion of participants who may have only had one 'treatment' session. This must be carefully weighed against the potential therapeutic contamination this may introduce into the study. A key aspect of this feasibility trial was to determine what the consent rate would likely be in a larger trial. The study was successful in obtaining this information.

The consent procedure worked well; parents attended all initial assessment sessions for young people aged 15 and under and there were no occasions where a parent and child disagreed on the young person's participation in the research. This

approach is in line with the National Institute for Health and Clinical Excellence (NICE) guidance (Guideline 28) recommending that family or carers of young people aged under 16 should be given information or support to help young people make decisions about their treatment (National Institute for Health and Clinical Excellence, 2005). Again this demonstrated the feasibility of the consent process for a larger trial.

A higher than expected proportion of those assessed using the Kiddie-SADS-Present and Lifetime Version (K-SADS-PL) met the criteria for Major Depressive Disorder (MDD). This could indicate that the study procedures for screening participants prior to this stage were effective at screening out patients who would be ineligible for the study. The complexity of participants at baseline may also indicate that these procedures were *too* effective and may have actually screened out potential participants with milder degrees of depression. All randomised participants screened positive for an anxiety comorbidity and had a high number of other comorbidities. Furthermore in our study, several participants and/or their families or clinicians highlighted these complexities as a barrier to engaging in BA treatment. This indicates that the advice provided to staff screening young people for study entry and the criteria on the participant study poster should be reviewed to attract referrals with a milder depressive symptomology. The additional referrals that would be created as a consequence of this, must also be considered.

Design

Trial design is a key factor when assessing study outcomes, as if there are weaknesses in the design one is unable to ascertain whether the intervention has

been ineffective or whether the results reflect implementation failure (Craig et al., 2008). Differing aspects of the BUDDY study trial design are discussed below.

Patient and Public Involvement

Previous research has highlighted the beneficial impact Patient and Public Involvement (PPI) can have upon research. One aspect of this is through involvement of stakeholders who raise issues not previously considered (Wilson et al., 2015). The PPI elements of the study, alongside the innovative focused ethnography to inform the trial from a staff and service perspective were beneficial in ensuring the trial was well adapted to the intended setting. In this study, when PPI input was obtained prior to the start of the trial, some suggestions (such as the amendments to the young person information sheets) challenged usual research practice and raised important ethical issues to be considered. Key messages from cumulative reviews of PPI in research suggest it is important to be sensitive to context and processes when designing studies (Wilson et al., 2015). The suggestions raised via PPI served to improve the materials and design, with the resulting trial recruiting the desired number of participants.

Risk of Bias

In addition to the potential bias in staff self-selection for the BA training, the distribution of staff (in terms of their pay grade and levels of experience) were unequal in the two arms of the study. In a future trial, using inferential statistics this is a source of potential bias in favour of Treatment As Usual (TAU). Firstly, staff in the BA arm were employed on a grade 7 or below due to the rationale that BA is easily disseminated to lower grade staff and those in the higher grades are already highly trained (i.e. Psychiatrists, Nurses, Clinical Psychologists). This means that the staff in

the TAU arm were skewed to be more highly skilled/experienced. However, the seniority of staff in the TAU arm combined with the less severe profiles of the young people (i.e. we excluded those requiring urgent care), may explain the lack of treatment seen in the TAU arm. It could be that senior staff held more complex or severe cases on their caseloads, which they prioritised over those young people in our study. This seems plausible in light of the difficult choices by staff navigating a lack of treatment resources, observed in the Stage I ethnography.

If it was found to be the case that senior staff held more complex caseloads, with a greater number of clients at risk of suicide for example, it could explain why clinicians did not prioritise the care of young people in the BUDDY study. The updates to the clinical guidelines for treatment of MDD in the DSM-V reflect the clinical needs relating to risk of suicide. A new specifier is available which aims to shed light on suicidal factors in patients who are depressed. These factors include suicidal thinking, plans, and the presence of other risk factors, in order to make a determination of the prominence of suicide prevention in treatment planning for a given individual (American Psychiatric Association, 2013). However, these developments are unlikely to have an impact on practice in current UK settings, due to CAMHS generally working outside of a diagnostic framework. There was no suggestion from qualitative interviews with staff in the BA arm that this may have been an explanation for the low rates of treatment in the TAU arm for their TAU colleagues.

One limitation of the trial design was that the qualitative exploration was limited to the BA arm so no staff or young people from the TAU arm were interviewed. Due to the way patients were allocated in the service it was not

possible to restrict staff in TAU to only those of a grade 7 and below; however, one way this could be achieved in future studies is by limiting the study intake to staff from Tier 2 of the service.

Similarly, the study design did not control for the number of treatment sessions in the two treatment arms. In the BA arm families were offered 8 BA sessions plus any additional care their practitioner deemed necessary, whereas in the TAU arm they were offered only the care their clinician deemed necessary. In almost all cases, this resulted in TAU participants receiving fewer treatment sessions than their BA counterparts, which is a source of bias as young people may be responding to the increased contact time provided rather than the intervention itself. Guidance on the reporting of trial results, recommends reporting the precise details of the intended treatments participants in each treatment arm will receive (Thabane et al., 2010, Eldridge et al., 2016a); although intended, this was not achieved in the BUDDY study. Standardising the content and delivering of a complex intervention in a RCT is a major challenge (Stephenson and Imrie, 1998). Treatment pathways recorded in the TAU arm demonstrate a lack of detail and inconsistencies in the patient records completed by clinicians. This makes it very difficult to ascertain the exact treatments patients have received and to follow their care through the service. One way to overcome these shortcomings would be to have clinicians record the exact treatment provided at each session in a standardised log for research purposes. This needs to be weighed up against ethical issues relating to storing this data and an additional burden on already overburdened workforce.

Pass and colleagues (2017) highlight the rationale for integrating Routine Outcome Measures (ROMs) into BA therapy in a UK CAMHS setting, as they allow the

clinician to track progress and monitor risk. In the BUDDY study, ROMs were rarely deployed by clinicians in either arm of the trial, which meant we were unable to use this information to assess whether young people who dropped out of treatment had done so due to an improvement in their symptoms. The reasons for this low deployment of ROMs are unclear. This contrasts with the aims of the CYP IAPT programme, which focuses on moving towards evidence-based delivery with clear monitoring of outcomes (using ROMs).

The study endpoint was specified before the data were collected and was not sufficiently long enough for all BA participants to have completed treatment. This meant that, for some participants, additional appointments were required to complete the qualitative interviews, increasing study burden on participants. It also may damage the integrity of the study in that some participants had not completed the intended course of therapy in some cases. This demonstrates the need for a larger trial to extend the duration of follow-up, possibly at six-months for the primary outcome measure, to ensure all participants have completed treatment.

Finally, the fact that qualitative interviews were offered prior to the main study endpoint at three-month follow-up could be a source of bias as it represents additional contact time for those in the BA arm. Qualitative interviews are usually experienced positively by participants and have been purported to have a therapeutic effect (O'Cathain et al., 2015), so this may have led to participants reporting more positive outcomes as a result. This needs to be weighed against the impact of interviewing participants several months following treatment, as this may impact upon the quality of data as they may have forgotten about certain aspects of

their treatment experiences but a benefit may be the ability to reflect upon the longer term outcomes of treatment.

Randomisation

The validity of a Randomised Controlled Trial (RCT) relies greatly upon the randomisation process (Akobeng, 2005b). As discussed in the methods section, randomisation is vital in a powered trial, as without a control treatment it is impossible to be sure that any response is due solely to the effect of the treatment and/or the importance of the new treatment in this population could be overstated (Akobeng, 2005b). It is difficult for a feasibility or pilot trial to effectively inform a larger RCT without introducing randomisation; using standard treatment as a control we took the first step towards a fully powered trial to investigate the effectiveness of the intervention in this novel population. However, the key purpose of randomisation in this feasibility study was to assess the acceptability of the two treatment options and observe the flow of patients through the study in order to inform a larger trial. Participants appeared to tolerate randomisation well (with only one young person declining participation explicitly due to the fact that they had to be randomised). This is a critical aspect of the future trial design.

Randomisation eliminates selection bias and minimises confounding variables, which are factors associated with both the outcome of interest and with the intervention (Kendall, 2003). A strength of the BUDDY study design was that the randomisation list was designed and implemented outside of the assessor's control. The randomisation process itself was not conducted satisfactorily due to errors allocating participants using distance randomisation. Although, there was no statistically significant differences found between the participants in two treatment

groups at baseline on depressive symptoms, self-esteem and functioning. This indicates these known confounding variables were equally distributed between the two treatment arms, this would be particularly important in a fully powered trial.

Excluding participant choice by allocating patients randomly to one or another treatment has been criticised in behavioural trials (Stephenson and Imrie, 1998). However, our findings from the qualitative interviews indicate that most young people in the BA arm did not report a preference for one treatment option over the other. In contrast, the end of treatment survey for the same participants suggests the majority would not have preferred TAU. This might suggest that young people chose a different answer on a self-report measure to the in-person qualitative interview. However it more likely highlights the benefit in qualitative interviews of being able to explore young people's responses in detail rather than restricting their responses. Those in the TAU arm expressed views in line with the qualitative findings in the BA arm, in that they did not have a preference towards either treatment option. If the findings of the interviews are most representative of the views of the participants, this suggests the study materials did not emphasise one treatment option over the other and both treatments were deemed acceptable treatment options to participants. This would suggest TAU, or combined treatment as it was referred to in the study materials, is an appropriate comparator for a larger trial. No disappointment was reported by young people being allocated to either the control or intervention arm, as has been reported in other research (Toye et al., 2016). According to MRC guidance, if this were the case it would need to be addressed in the subsequent trial design. If trial participants have strong treatment preferences they may refuse to take part or drop-out if they did not get their desired

treatment. This undermines the advantage of randomisation (Craig et al., 2008). If they remain in the study it could impact upon their compliance with treatment. Lack of acceptability of the intervention may lead to failure of RCTs due to poor recruitment if patients are not willing to be randomised to both treatment options (Lancaster et al., 2004). The importance of an appropriate comparator can be seen in a recent US trial of BA for young people, they recruited only one young person (aged 13 to 17) in 14 months to a trial of BA or Fluoxetine (medication) (Craighead, 2017).

There are learning points from the BUDDY study that could be utilised to inform a larger trial:

Firstly, the use of secretaries to staff the remote telephone randomisation was a pragmatic choice but using staff inexperienced in research can, and does, lead to errors which impact upon the quality of the trial. In a future study, a remote randomisation service would still be beneficial but the use of a professional clinical trials unit for remote randomisation would be superior.

Secondly, the blocked randomisation resulted in equal groups but the stratification increased the complexity of the allocation process, which may increase the chances of technical error (as occurred) and was also inflexible to changes within the trial once the randomisation list had been finalised. This inflexibility could have been disruptive when a service restructure occurred during the recruitment period where two of the sites were restructured (Tier 2 and 3 were amalgamated), however in this case as the teams were still identifiable in their old format (i.e. the original staff were retained except for a manager) we were able to continue using the same randomisation lists. This could be minimised by the use of a professional trial service

(and statistician) to oversee the randomisation process and by not stratifying by Tier, instead, this could be controlled for in a larger trial in the statistical analysis.

Thirdly, another difficulty that arose during the trial was the timing of the randomisation. In some cases this occurred too early in the study and may have led to increased rates of drop-out (i.e. the time lag between randomisation and start of treatment meant those who dropped out or were discharged prior to treatment were already randomised into the trial). It was difficult to identify the point at which patients would start treatment as they may have been allocated to a clinician but would remain on their caseload often for many months without active treatment. Potentially randomisation could be completed at a later point rather than as soon after the diagnostic assessment as possible, however this needs to be weighed up against the risk of causing treatment delay. One aspect that was not adequately accounted for in this study is that the block size did not vary, it is recommended in unblinded studies that mixed block sized are used to prevent the last allocation in each block becoming predictable (Kendall, 2003).

Another learning point to reflect on, related to the format of the randomisation used. The BUDDY study utilised 1:1 randomisation. With the benefit of hindsight, an unequal randomisation of 2:1 in favour of the BA intervention would have been preferable for this feasibility stage. Doing this would have enabled each clinician in the BA arm to have been allocated a greater number of participants within the trial. As it was, clinicians only treated on average 1.8 randomised patients during the trial. As the BA intervention is not well-established in this population, this amendment would have provided important additional experience to staff delivering the intervention and a greater variety of cases for them to reflect on during the

qualitative interviews, whilst still allowing the study methods to have been adequately tested. That said, 1:1 randomisation remains the best choice for the subsequent fully-powered pilot trial because it provides the greatest power for testing effectiveness (Eldridge et al., 2016a).

The importance of prior experience and expectations has been an enduring aspect to both Stage I and Stage II of this study. The qualitative interviews suggest that most of the young people did not have a full understanding of the treatments being presented to them, despite being provided with comprehensive written study materials. This suggests that other more novel approaches for educating young people about their care options may need to be considered. One option, suggested by NICE, is the use of more computer technology (National Institute for Health and Clinical Excellence, 2005). It may be that these technologies could be utilised to make accessible descriptions of the treatment options in the form of videos for example. Most young people had no prior expectations of what their treatment would consist of. As expected, with more life experience, the parents generally had different expectations to their young people. While outside the remit of this study, future studies might explore whether these prior expectations of treatment exert any influence upon patient outcomes.

One unanticipated finding from the qualitative interviews related to the power of decision-making; young people were happy to remain open-minded to different treatment approaches perhaps expressing a trust in the CAMHS service and a reliance upon their professional or parent to make the right decision for them. This seems to be at odds with the mainstream push to have more patient-directed care in the National Health Service (NHS) as a whole. This move towards user-led research

(Mawn et al., 2016) may not have been successful in this environment where the traditional authority of the clinician still predominates. Wilson (2015) documents the history of the unquestioned authority of medicine and a sense of disillusionment from service user groups over health care decisions that are made without input from service users. This passivity was also evident in the preference by at least one parent for hypnotherapy and a family who requested medication (rather than psychotherapy), which may mean that treatments that do not involve active participation could be more attractive.

As discussed earlier, this population were vulnerable in terms of their age. The findings from the BUDDY study suggest this is perhaps an area where more attention should be paid. Age may be an important inhibitor to psychological therapies that rely upon patient participation, which could be explored in further detail. This again emphasises the importance of seeking PPI input from both young people and parent/carer representatives. Despite a growing recognition of the importance of experiential knowledge being addressed alongside scientific understanding, there is also a clearly often an intrinsic resistance to acknowledging lay knowledge in relation to PPI (Wilson et al., 2015).

Blinding

Blinding to treatment allocation in clinical trials is intended to prevent the expectations of patients or researchers from influencing the outcome (Stephenson and Imrie, 1998). Blinding is seen as one of the most effective ways to reduce the chance of a biased result (Eldridge et al., 2016b, Eldridge et al., 2016a). A major limitation to the design of this study was the risk of assessment bias when the patients, parents, clinicians and the assessor were all aware of the treatment

allocation, which may influence the recording of signs and symptoms (Petrie and Sabin, 2009). The BUDDY study results suggest this may be the case, as the trends on the Children's Global Assessment Scale (CGAS; judged by the assessor) were the only measure where an opposite trend was shown for participants in the TAU. One control to prevent this was to use a combination of self-report and assessor-administered assessments, as well as structured tools that are less dependent upon the assessor's subjectivity. The use of self-report may have reduced the risk of assessor bias; however there is an increased chance of performance bias (where participants give an answer they believe the assessor is looking for).

In the BUDDY study, ideally as a minimum, the assessor would have been blinded to treatment allocation to avoid this source of bias but as the sole researcher responsible for all aspects of trial implementation concealment was not possible within the resource restraints inherent in a PhD project. In other large psychotherapy trials in both adults (Richards et al., 2016, Gilbody et al., 2017) and young people (Goodyer et al., 2017) it is accepted convention that participants and clinicians remain unblinded. A double-blind trial would not have been possible because it would have been unethical to blind patients and their parents to the treatment they were receiving. These limitations were offset to some degree by the fact the assessor was masked to the randomisation list so it was not possible to influence randomisation or treatment allocation. A key recommendation from this feasibility work is that in a future study, the assessor should be blinded to treatment allocation and a trial statistician should conduct analyses blinded to treatment outcome to reduce these sources of bias. Tindall and colleagues (2017) found all three of the RCTs conducted in the area to date did not blind participants or

personnel to treatment allocation meaning they all have a high risk of bias when evaluated using the Cochrane risk of bias tool. However in all included trials, the assessors were blinded to the outcome assessment demonstrating a low risk of bias in this respect, whereas in the BUDDY study it would be high. Without effective blinding of the assessor responsible for completing the outcome measures bias may be introduced into one arm not present in the other (i.e. because assessor may intentionally or unintentionally provide extra attention to those in the treatment arm (Kendall, 2003).

Clinician's beliefs in relation to the two treatment options being offered are important. Clinical and personal equipoise (Cook and Sheets, 2011) exists when a clinician has no good basis for a choice between care options. A lack of equipoise (O'Cathain et al., 2015) can lead to a lack of utility of the evidence in the real-world of clinical practice. It can be addressed by researchers through education or by increasing awareness and enabling open discussion. In this case, the qualitative findings demonstrate a lack of equipoise for some staff members. This may lead to bias, and could account for a proportion of the 'effect' that would traditionally been assigned to the intervention (Cook and Sheets, 2011). This also highlights a potential impact of the lack of blinding in this study, as the clinicians may have over compensated for their lack of faith in BA by providing 'extra' care, again leading to bias (Akobeng, 2005b). This is of crucial importance in a larger effectiveness study because it could lead to the overestimation of the treatment effect, if additional care over and above what is recommended in the manual or what has been declared is provided by clinicians. It was evident from the reasons clinicians provided for withdrawing patients that had been referred to the trial, as well as feedback from

some clinicians in the qualitative interviews, that CAMHS staff had preconceived personal preferences relating to the ability of TAU to provide better outcomes than BA treatment. Although this may be an unconscious bias, it is an ethical issue in trial design.

Research paradigm

Mason (2006) has suggested that viewing social phenomena and lived realities along only one continuum (i.e. positivist, trials-based knowledge) may lead to researchers experiencing an 'impoverished' understanding, while mixed methods allows access to multiple viewpoints and dimensions. This highlights the parallel insights gained through mixing methods (Cresswell, 2009), in this case through the experience of different stakeholders; the clinicians, patients and their caregivers. One illustration of this was when different families had very different perspectives on the level of involvement that parents should have in their young person's treatment. This is where the qualitative and quantitative mixed methodology enabled an in-depth exploration of these differing viewpoints that would not have been achieved by using either approach in isolation. Some parents and young people were in agreement, whilst others had vastly differing opinions on the subject. This raises the question for clinical services and research studies; whose viewpoint should be given greater weight to when families disagree about the level of parental involvement? Several families mentioned the difficulties of working through issues during therapy with some discussing the benefits to their families as a result of this and others reflecting on an ability to tackle these difficulties. It is interesting that the clinician perspectives differ markedly from the young people's comments relating to parental participation. One young person suggested how helpful parental involvement was,

even if it was initially undesirable, as an aid to "getting back to … normal things". Furthermore, as discussed earlier, the survey data demonstrated that a sizable majority of participants made simplistic responses that, in later qualitative interviews, were shown to be complex issues. If solely survey outcome data had been collected, this would have been at worst misleading or, at best, represented a missed opportunity.

Upon reflection, Stage I of this thesis (the focused ethnography) helped to determine my approach to the qualitative components of the trial; I found myself wanting to collect contextual information that I was exposed to *during* the trial, rather than in the post-hoc qualitative follow-up interviews with participants or clinicians. One example of this was watching young people attempting to complete the BADS measure; in almost all cases young people asked me or a parent how they should complete the tool or asked for help understanding the language used in the questionnaire. Not only has this shaped my desire not to use this measure in a future trial, but it would have been useful to systematically record this ethnographic information to inform the selection of a more appropriate tool.

Treatment Uptake

The numbers starting therapy were similar (at 82%) to those reported in a large-scale psychotherapy trial of adolescent depression, the IMPACT study (87-93%; Goodyer, et al., 2017). The young people who started BA treatment received a high number of the intended BA sessions. This contrasts with the IMPACT study, where participants received fewer treatment sessions than anticipated. Most young people attended the number of session assigned by their practitioner (i.e. completed the full 8 session

course of BA), as in previous research in young people (March et al., 2007, Ritschel et al., 2016).

Treatment delivery

Setting

The CAMHS as a setting was successful but one family commented on a lack of flexibility as their clinician did not work after school hours. This was the primary reason for selecting CAMHS over the school setting used in the BODY and mind study (Arnott, et al., 2012) but in this families case it appeared to be the result of this particular clinicians working hours. In other respects, the setting of the BUDDY study seemed appropriate to deliver the BA intervention.

Treatment as usual

Most young people allocated to the TAU arm, remained in the service for six months and received little treatment for their significant mood difficulties. This is in keeping with previous nationally representative research in Britain, which reported low numbers of treatment sessions for those in contact with services (Ford et al., 2003). This reflects the findings of the focused ethnography and previous literature where commentators have reported concerns over the content of therapy sessions (Olubokun, 2017). This is further justification for a manualised approach across both treatment arms.

Behavioural Activation

Materials

Several clinicians liked the manual materials but most felt there were too many worksheets. As McCauley and colleagues (2011) found, less is more in terms of a BA

manual and that the key component of BA, its simplicity, easily gets lost. This was less of a concern for the young people involved in the BUDDY study and may reflect some clinicians' usual procedure of providing care without worksheets. From a clinician perspective, there was a need for more 'practice' time to focus on goal setting and activity scheduling and a less structured, more flexible format for therapy.

Previous research has noted that therapists often rely upon an eclectic mixture of therapeutic approaches in order to treat young people (Ford et al., 2003). Staff made their own adaptions to the manual to fit the manual material into 8 sessions. The rigid structure of the manual was felt to be too restrictive for more experienced clinicians who usually provided care using an eclectic style of mixed therapeutic approaches. Commentators note full treatment protocols may not be appealing to clinicians in clinical practice who may wish to blend newly acquired skills with existing skill sets (e.g. Rutter, 2008). Some clinicians in the BUDDY study reported the BA manual hampered their treatment delivery style and restricted them from following their intuition. And, as found in previous iterations of the manual (McCauley et al., 2011), this emphasis on early structure may have encouraged some clinicians to overlook or delay work on key treatment targets. In contrast, this structured format was felt to be helpful to guide sessions by less experienced clinicians. Future iterations of the manual should focus on better utilising the existing skills of CAMHS practitioners and allow delivery with flexibility and individualisation. Previous research (Davidson et al., 2014) utilised a speak-aloud technique to inform the design of a computerised BA depression module for

adolescents. This approach may be useful in identifying the relevant part of the manual that require updating.

Riley et al (2005) suggest privileging the view of the people administering the intervention over those of university researchers, as they infer clinician's views are likely to be closer to 'reality'. This suggests, as utilised in the focused ethnography, that this "captured wisdom" (Webber, 2014) from clincians, will be useful in improving the relevance of the manual to the CAMHS setting. As the MRC guidance states, ensuring strict fidelity to a protocol may be inappropriate if there is knowledge that the intervention may work better if adapted to the local setting (Craig et al., 2008). This suggests that future iterations of the manual may need to be flexible enough to adapt to the specific local context. Considerations such as these are important, because a manual is of no use if it conflicts with deeply entrenched values in the setting (Craig et al., 2008). Our research suggests clinicians' views relating to manualised treatment should be explored further.

Staff Training

The qualitative findings have provided rich data illuminating aspects of treatment experience and delivery that otherwise would have been inaccessible. We found staff below grade 7 across Tiers 2 and 3 were able to deliver the intervention and most of them found the training and delivery acceptable. This is particularly important for the rationale of choosing BA over other more specialised psychotherapy options such as Cognitive Behavioural Therapy (CBT). However, there were some training related concerns. Treatment pathways were interrupted for a variety of reasons. Improvement in the young person's condition was given as a reason for not embarking on or continuing with treatment, whereas suspected

cognitive impairment was a reason for suspending the progression of sessions. In two of these cases there were suggestions that treatment was not delivered as per protocol and termination appeared premature. This was explored with one staff member but the other team member was unable to schedule time for a follow-up qualitative interview. It was not clear from our results, whether this was related to inadequate training or other difficulties. It may be that service pressures led to pressure from outside of the study for clinicians to discharge patients that they did not deem 'risky'. This was supported by evidence from another staff member (Geoff) who cited their difficulty with the eight-session format, was it being suitable for the young people but not feasible within the CAMHS service due to external pressures. This suggestion is particularly concerning for trials that rely upon training existing NHS staff to deliver interventions in a pragmatic trial design such as this, and is an issue that could have been explored further if the ethnography from Stage I had been extended for the whole trial duration.

Supervision

Clinical supervision was found to be important to staff in this study, reflecting previous work in specialist CAMHS (Edwards et al., 2008). Team supervision was utilised in the BUDDY study, as others have done whilst applying BA to adolescents (Ritschel et al., 2016, McCauley et al., 2016), as recommended in Stage I of this research. This approach was well received and supervision was well attended.

Delivery Format

As in our study, other intervention trials found families reported it difficult to fit BA sessions in around school and existing commitments (Toye et al., 2016). Although context specific, our findings highlight young people experienced barriers to care,

which may be transferable to other treatments delivered in this setting. As in previous work, young people valued regular, pre-organised appointments (Affleck and Seed, 2015). Interestingly, greater gains have been observed in the first 9 weeks of treatment in other BA research (Ritschel et al., 2016), supporting the 8-session format. The weekly format was popular, however both clinicians and young people felt the tapering of treatment sessions towards the end of the programme would facilitate greater autonomy whilst retaining a level of support. Families were overwhelmingly in support of delivery on a weekly basis and were generally happy with the length of sessions. Again, the only opposing voice was David, one of the young people with an ASD; this may mean that BA treatment needs to be adapted for people with additional needs. Previous adaptations to BA treatment have included a period where young people can opt to focus the BA sessions on any outstanding issues (Ritschel et al., 2016). In other studies, additional flexibility has been offered via top-up sessions (such as in Richards et al., 2016). Gaynor and Harris (2008) suggest a stepped approach to BA care where more complex participants who do not respond to basic BA (i.e. activity monitoring/scheduling and values-focused work). Our findings also support a modular approach, which may have the added benefit of allaying clinician's fears that BA "is not enough". This may have been redressed by adding follow-up sessions at a later date or delivering the final sessions over a longer time period. NICE recommend that patients in remission from depression should be reviewed regularly for 12 months (24 months if it is recurrent depression) by an experienced CAMHS clinician; if remission is maintained, then they can be discharged into primary care (National Institute for Health and Clinical Excellence, 2005). The guidelines suggest this should take the form of follow-up

psychological therapy sessions to reduce the likelihood of, or at least detect a recurrence in, depression in those at high risk of relapse. Ritschel, Ramirez, Cooley and Craighead (2016) note that this flexibility is a pragmatic approach that is more reflective of clinical practice.

Parental Involvement

As in previous research (McCauley et al., 2011), parental involvement was key to avoiding barriers to treatment. This was particularly the case for external barriers, such as financial or transport provision. This led to problems for young people desiring autonomy but encountering parents as the gatekeepers to the required resources. This echoes the report of a previous, unsuccessful case study where manualised BA was delivered to a young people with depression in the USA (McCauley et al., 2011. One barrier identified was restricted access to a family car by parents, which acted as a barrier to the goals set by the therapist. Interestingly McCauley and colleagues (2011) also observed conflict between the clinician maintaining the therapeutic relationship with the participant and the need for parental involvement. In fact, a lack of contextual information about the adolescent's home life hampered clinician effectiveness (McCauley et al., 2016). As in the BUDDY study, this meant clinicians missed vital information about obstacles and barriers to activation. In the BUDDY study, some clinicians felt parents needed to be more involved in their young person's treatment, a view not always shared by the young people they were working with. We observed pairings of young people and their parents where caregivers understood the BA rationale; as such, they were able to observe the impact of their young person's depression and support their activation. In contrast, however, in one case the young person's parents themselves

were the barrier to treatment and refused involvement when invited by their clinician. As in previous reports (Affleck and Seed, 2015), young people reported that they valued the option of involving their parents in their treatment sessions. Emphasising the need for an individual plan for parental involvement in BA treatment.

Previous adaptions to BA treatment for adolescents added in parental involvement at the beginning, middle and end (Ritschel et al., 2016). Our findings suggest the need for a more flexible approach, utilising the experience of the clinician in order to tailor the treatment to each individual. In adults, BA has been successfully adapted for patients with intellectual disabilities and depressive symptoms with the most notable adaption being the inclusion of a significant other during treatment (Jahoda et al., 2015): in this study, of the two participating young people with an ASD, one had a parent present and one did not. Further illustrating the need for an individualised approach.

Parents mentioned their own mental health and the impact it had upon their young person's care. NICE guideline 28 (National Institute for Health and Clinical Excellence, 2005) suggests parent's own psychiatric problems should be treated in tandem if the young person's mental health was to improve. This was not possible within the restrictions of this study but could be an important and interesting avenue to explore in future research.

Individual Factors

One thing that stood out in the young people's descriptions of their journeys through treatment was the role of individual or family motivation. A parent of one young person who did not complete treatment stated they would have preferred their

young person not to be an active participant in treatment, whilst their young person said they were too tired to engage. Another young person, who completed treatment, suggested they knew they needed help but that it had taken them two years prior to treatment to get to a point of acceptance that they needed assistance to move forward. They went on to say some other young people may not yet be in the right place to accept the help offered or to accept that they can't be "fixed". Turner-Halliday (2014) described a similar concept in CAMHS which they termed 'readiness': that is, that young people must be in the right place to embark upon therapy. This was evident from some young participants in the BUDDY study. The authors extend this concept to parents (Turner-Halliday et al., 2014), in the sense of whether they are ready to support their young person through therapy. In some cases, parents did not provide an optimal environment for their young people to undertake treatment whether this was due to their own mental health problems or through acting as a gate keeper for needed resources.

The BUDDY study sample displayed higher rates of anxiety comorbidity (all young people screened positive for generalised anxiety disorder) than reported elsewhere where rates ranged between 30-80% (Birmaher et al., 1996), but this most likely represents our use of an anxiety screening rather than diagnosis tool. Rates of anxiety in the sample are relevant, as higher anxiety levels may be related to increased likelihood of disengaging from therapy; in a previous RCT of BA in the USA; anxiety was reported to be a contributing factor to treatment drop-out (McCauley et al., 2016). Future trials could use an additional measure of anxiety.

The BA therapeutic approach was viewed by clinicians and some young people and their families, as unable to meet the needs of patients with multifaceted

symptom profiles. Some clinicians felt CBT may be better placed to address thinking errors. One young person also reported that BA may have helped their low mood but left other comorbidities such as their anxiety untreated. This may illustrate the difficulties of implementing a treatment focused upon one diagnosis in a clinical population with multiple complex symptoms. As Kessler and Glasgow (2011) also found, there were difficulties working with young people with multiple needs, those who were disruptive or stressful, or had unsupportive home lives. Similarly, some clinicians felt BA didn't provide enough "tools" to deal with young people's comorbid anxiety. This echoes NICE Guideline 28 for depression (National Institute for Health and Clinical Excellence, 2005), which states comorbid diagnoses should be assessed and treated in sequence or parallel with depression. It may be that, due to the high levels of anxiety seen in this population and, with all young people entering the trial suffering comorbid anxiety symptoms, the manual needs to incorporate a greater focus on treatment of these symptoms. Previous feasibility work has looked at this in a group therapy context in the USA (Chu et al., 2009) and BA in collaboration with exposure therapy to specifically target anxiety symptoms in individual therapy (Weersing et al., 2008, Weersing et al., 2017).

Therapist Factors

As previously mentioned, some staff did not have confidence in the BA approach, with some stating that BA was insufficient as a stand-alone treatment or that cognitive skills were required to bring about improvement. In a previous case study of BA, researchers found it was important that the clinician had faith in the ability of BA to bring about change (Pass et al., 2017). In the BUDDY study it was unclear how widespread these concerns were in the broader CAMHS team. In the staff interviews,

one staff member had strong feelings relating to the limitations of BA treatment. However, for most staff, concerns were related to specific aspects of care in certain cases rather than a broader lack of faith in the treatment. In fact, most staff expressed the value of the approach for treating depression.

As in previous research (Affleck and Seed, 2015), young people valued working with CAMHS staff. In the context of therapy, NICE recommend therapists should develop a treatment alliance with the family (National Institute for Health and Clinical Excellence, 2005). Therapeutic alliance refers to how well client and therapist work together (Rutter et al., 2008). A meta-analysis of studies of therapeutic alliance over a range of treatment childhood modalities found an effect size of 0.21 for the effect of alliance (Shirk and Karver, 2003). This was raised as a concern by some therapists in the BA arm as they felt a manualised approach may damage this delicate relationship. Feedback from young people did not provide any accounts where this was the case. On the contrary, young people and their families highlighted the therapeutic relationship as a key facilitator in their engagement with the BA treatment.

Impact of Treatment

As discussed previously, there was some evidence that young people lacked control over their lives and experienced restricted autonomy; this is an important consideration, as lack of control has been indicated as a cause of youth suicides (Patel et al., 2007). Experiencing comorbidities alongside their depression made it difficult for some young people to complete, participate in or excel during BA treatment; however, a key facilitator appeared to be the practicality of the treatment approach. As one young person articulated it, “doing the things you talked

about doing". Furthermore, young people and their parents highlighted how important the role of the therapist was, both in terms of the therapeutic relationship but also in simply having someone available to listen to what the young person had to say. The downside to this security was that when it was taken away (at the end of the manualised treatment sessions) some young people felt lost and lacked confidence that they could keep up changes that had been made or make suitable improvements in the future. One reasons suggested for this (Pass et al., 2017) is that clinicians become a source of positive reinforcement, which is then lost at the termination of sessions. Participants offered some suggestions for improvement, such as additional review or relapse prevention sessions following treatment.

Young people also had some interesting reflections to offer on the barriers to treatment. One young person reflected upon their friendships and the links this may have had in maintaining their own depression. Most striking was how these insights echoed the focus of the BA treatment manual in identifying relevant internal and external barriers to increasing activation to improve mood.

Overall, most young people and their young people reported positive outcomes in the qualitative interview, such as improved family relationship, increased variety of interests and activities, increased self-esteem and motivation, and decreased depressive symptoms. These positive impacts were supported by the quantitative data, which generally showed improvements across mood, self-esteem and functioning outcomes in both treatment arms. Although greater improvements were seen in those in the BA arm. Young people and their parents also reported high treatment satisfaction ratings on the end of treatment survey, finding BA was helpful and enjoyable. In this study young people found BA treatment had a wider impact on

their family relationships and valued the improvements observed. However, young people's relationships with the outside world were a barrier to treatment, and BA did not enable all problems observed to be addressed. Furthermore, where they might have been expected to take ownership of these difficulties, young people found it difficult to do so and often placed the blame on others, such as friends/family.

Behavioural Activation Techniques

There are outstanding feasibility questions relating to the feasibility of delivering manualised BA in this context, as there was evidence that staff were adapting the manual to suit their own needs and expertise. In two cases in particular, there were suggestions that BA was not being delivered in the prescribed format and staff held diverse views on treatment delivery. Two staff members reflected upon the impact of their previous background in terms of therapy provision, with one finding BA matched well and the other finding the opposite. This is reminiscent of the individual differences dependent upon staff background, observed in the ethnography in Stage I. Similarly, Wells and colleagues (2012) found interventions were delivered differently depending upon the staff member. Generally, staff in the BUDDY study were positive about the BA approach and found it acceptable. Clinicians have previously been found to reject complex interventions because they do not fit with their normal practice (Wells et al., 2012). This may lead to clinicians acting as gate-keepers deterring young people from receiving the treatment in practice; there were suggestions that this may have been the case if BA was to be implemented in its current form at this CAMHS site. This is building a strong argument when added to

the findings from Stage I about the individual differences between staff and how they relate to providing a manualised treatment.

Another criticism of the use of manuals in psychotherapy is that it undermines the therapist patient relationship and restricts staff drawing on range treatment models (Goldfried and Wolfe, 1998). Although one staff member felt this, the young people working with this clinician did not agree. Generally, the participating young people and their carers reported building positive therapeutic relationships with their therapists and vice versa. This positive therapeutic relationship was viewed as crucial to the success of therapy and families did not feel it was hampered by manualised delivery of treatment.

Some staff found it difficult working with difference (such as young people with ASD), and although surprising, this has implications for service delivery. It did appear that one young person with ASD in the study encountered their comorbidity represented a barrier to treatment whereas another young person with ASD did not. In the case of David, it was his rigid devotion to a niche interest that presented a barrier to activation. As this interest had been identified during the values based activities during the initial BA sessions, it was natural that the clinician and the young person attempted to schedule activities relating to this hobby. However, when these were deemed to be unrealistic, treatment stalled. It may be that for some young people with ASDs, that such a rigid mind-set might be incompatible with such a treatment. In contrast, however David reported on other activities that he was able to schedule effectively (such as cooking for himself).

Activity monitoring serves to provide information on activity levels and related mood to inform activity scheduling and to demonstrate meaningful links

between activity and mood to client (Gaynor and Harris, 2008). Activity scheduling targets a variety of activities in a client's life related to pleasure, mastery, goals and values, problems to be solved, areas of avoidance etc. determined with the therapist collaboratively (Gaynor and Harris, 2008). It was goal-setting and activity monitoring that most young people, their parents and clinicians chose to focus on as the most important part of BA therapy. There was evidence this technique had been deployed successfully for many participants.

Outcomes

It is not appropriate to place undue significance on the quantitative results as no formal power calculations have been undertaken (Lancaster et al., 2004). The reason for this is that the Confidence Interval (CIs) are likely to be imprecise even when there are significant differences. We have treated the quantitative results as preliminary for this reason and emphasised the descriptive findings. In this study, all participants who attended follow-up completed outcome measures fully, with only one instance of missing data. This was due to the way in which the questionnaires were administered, which provided an opportunity for the assessor to check the data whilst patients and their families were still present.

Attendance at follow-up appointments, however, was low. Barlow (1981) cautioned that since some people always get better no matter what one does, there is ample opportunity for clinicians or researchers to attribute their success to their particular intervention. Both BA and TAU were associated with improvements on a variety of outcome measures (apart from on the CGAS measure for those in the TAU

arm). There was an absence of adverse events and decreases in symptoms in both treatment conditions, which is encouraging for reduction of morbidity.

As this was a clinical trial we were interested in measuring the impact of BA treatment on a variety of outcomes, however without the study being powered, we cannot draw meaningful conclusions from these findings. According to the exploratory analysis, when the small sample size was controlled for, the result reached borderline statistical significance indicating remission from MDD in BA at three-month follow-up may be more likely in the BA treatment group compared to TAU. Moderate to large effect sizes were seen at three-months in Mood and Feelings Questionnaire- Child (MFQ-C) scores in the BA arm. Very small to small improvements in self-esteem were seen in BA compared to TAU. Functioning effect sizes at follow-up in the BA arm were moderate to large. The descriptive statistics indicate trends towards improvement in the numbers meeting the diagnostic criteria for MDD, the severity of those who still met MDD criteria, numbers of comorbidities, child and parent-reported depression at three-months and self-esteem across both arms of the study. There was a tendency to observe greater improvements in the BA arm. There was also a trend towards improvement in functioning in the BA arm but not TAU. This may reflect bias on the research rated measure, as discussed previously. However, translating these research findings into clinical practice requires more targeted research. The analysis was post-hoc, in a future trial a statistical analysis plan in advance to avoid 'mining' the data.

Tindall and colleagues (2017) note that seven of the 10 studies in their systematic review used the Children's CDRS-R (Poznanski and Mokros, 1996). A measure which demonstrates good inter-rater reliability in an adolescent population.

This may be an alternative to the lengthy K-SADS-PL. Half of the studies included in the systematic review included a measure of anxiety. Although we measured anxiety as a comorbidity, we didn't measure it using the full K-SADS-PL anxiety diagnosis, which may offer more accurate insights to comorbidities but would add to an already lengthy assessment procedure.

As in previous research (Ritschel et al., 2016) where 32% of the sample sought ongoing treatment, some young people were provided with further treatment following BA therapy. In a future trial, the content of this treatment should be closely monitored.

Previous commentators have highlighted conducting underpowered trials as unethical, but they are acceptable in the context of a feasibility/pilot study as long as participants are informed of this (Thabane et al., 2010). To date, BA interventions have mainly been evaluated using uncontrolled before and after comparisons. Dissatisfaction with these comparisons is partly related to the statistical law known as regression to the mean (Stephenson and Imrie, 1998). If extreme values are singled out from a distribution, they are likely (for purely statistical reasons), to fall closer to the usual level if measurement is repeated. In the absence of a control group, lower ratings at follow-up may merely reflect the law of statistics (Stephenson and Imrie, 1998) but be wrongly attributed to the effect of an intervention. As such, progression to a pilot and future definitive RCT would add greatly to the literature.

Attrition

The number of participants dropping-out from treatment is an important element in trial design. Missing data were anticipated and treatment drop-out was in line with

previous research; dropout from active psychotherapies such as BA is commonly high (Clarke et al., 2009). Similar numbers dropped out in both treatment arms and no differences were observed between completers and drop-outs. This suggests there is no evidence of attrition bias. The greater the drop-out, the less reliable the results of the study in a definitive trial (Everitt and Wessely, 2008), so it is useful to assess whether any changes to the protocol could be made to encourage participants to engage with the study follow-up.

A greater rate of follow-up was achieved when the assessments were conducted in-person at three months, compared to the telephone follow-ups at six months. This may be because the telephone follow-up occurred later than the in-person one at three months. Another reason for this may be that some families did not have a telephone so I had to call other family members, which complicated the process. The higher rate of follow-ups at three-months could be due to the fact that many young people were still receiving treatment at that point (so were engaged with the CAMHS service and used to attending the site) or the fact that they preferred face-to-face assessments to telephone ones. It might have been useful to trial alternative settings (rather than CAMHS) for the follow-up sessions, such as home visits or One Point centres because participants, who were no longer receiving treatment (particularly if they had been discharged), may have felt unwilling to re-visit CAMHS (especially if they had not had a positive experience). Previous reports have highlighted home visits as an acceptable environment for young people (Affleck and Seed, 2015).

Strengths

The results of this feasibility trial are generalisable in the sense that they can be used to inform a larger trial of the BA intervention in this setting or similar trials with a similar population. We recruited from a clinically referred sample and used limited exclusion criteria, so the results should be relatively representative of the CAMHS population from which they were recruited. Weisz et al. (2005) highlight the importance of clinical representativeness in psychotherapy studies. They note three criteria in particular that indicate whether a study is likely to demonstrate good clinical relevance; clinical representativeness of young people sampled, therapists who provided the treatment and the delivery setting. On all three fronts, the BUDDY study was successful with high external validity; the young people were help seeking, recruited via usual referral routes with minimal exclusion criteria, and therapy was delivered by clinicians from the setting, in the intended setting. In Weisz and colleagues' (2005) quantitative methodological review of youth psychotherapy studies, only 1% of the 236 studies from between the years 1962 to 2002 met all three criteria.

Generalisability is the extent to which aspects of a study can be applied to other circumstances (Eldridge et al., 2016a). The small size of the study restricts our ability to comment on the implications of this study for routine clinical practice. We used a broad inclusion criteria to enhance the generalisability of our results; however the results are from three CAMHS teams in the North-East of England and may not be representative of other areas of the UK or the world. Our results represent the activities of one feasibility trial, but may reflect some of the challenges other researchers may face in conducting research in similar settings.

We analysed participants in the group to which they were randomised (ITT) (Kendall, 2003), which is important to avoid bias. Although the interpretations of the results have been limited by the study design and introduction of bias, many of the study objectives have been achieved. We were able to effectively recruit and retain staff and participants in a complex clinical setting. We were able to assess which recruitment methods were robust and which need to be adapted in future work in this setting. Behavioural Activation appears to be acceptable to the majority of lower-grade clinicians, young people and their parents. The pragmatic approach to trial design led to a comparison of viable, clinically relevant alternative treatments, in a study with good external validity. This highlights a major strength of this study which was it was conducted in the reality of a busy CAHMS service by staff from the team, rather than a controlled research setting. This setting provides insight into the realities of implementing a treatment such as BA into clinical practice. Clinicians from the NHS were trained to administer the BA in this study. This is particularly pertinent when compared to some of the US literature where potential participants are recruited through advertisements, so were not help-seeking and may have been offered free treatment.

We evaluated BA against a strong treatment comparison in which skilled therapists predominated. The BA given was standardised to some extent by a structured session-by-session treatment manual, although treatment fidelity was not assessed. The BUDDY trial builds on the previous work in the field; being the first study to introduce randomisation in a UK secondary care setting and to qualitatively explore (using a formal methodology) the experiences of staff delivering the intervention alongside those of the participants and their parents. Without this

qualitative element, the trial would have been at risk of editing out the complexity of young people's, their parent's and staff's experiences of the novel treatment, in search of the general picture provided by the collation of quantitative outcome measures. This qualitative aspect to the trial has yielded the most insightful findings and can be used to refine the future intervention and trial design to inform a larger trial.

A standardised validated diagnostic interview was used to assess depression status, addressing previous criticisms of UK-based literature. Remote randomisation was used to remove the researcher from the process of participant allocation to treatment, which removed a potential source of bias. Selection bias was controlled for so there was a low risk of bias due to independent random sequence generation and allocation concealment.

Limitations

A major weakness is the number of confounding variables that may have influenced the data. This pragmatic trial, conducted in a busy CAMHS team, means that it is not possible to quantify or control for the contribution of antidepressant medication to outcome, although all participants were on a stable dose (of medication) at the outset of the trial, we did not monitor medication during the trial. This is important as we did not restrict clinicians from prescribing during the trial so it is possible that young people may have initiated new medication regimes during the trial. This represents a confounding variable. The number of BA sessions was controlled but not in the TAU arm; so therefore, any positive results could be due to the effects of meeting with a therapist rather than the BA treatment itself. Young people in the BA

arm received more treatment sessions than those in the TAU arm, which may account for the positive findings. The qualitative interview may have added to this inequity. Equally, due to the absence of measures for the quality of BA treatment (fidelity was unable to be assessed) there may have been contamination (for example, some BA therapists had previous CBT training). Contamination has the potential to impact upon the results and could lead to the misrepresentation of the treatment effect in a larger trial. This would be particularly important in light of the indications from staff and participant interviews, which could indicate weak or erratically implemented treatment. Not all clinician referrers or practitioners delivering BA, adopted a position of clinical equipoise, which is integral to conducting a high quality trial. Blinding was not feasible in the study, which means there was the added potential for contamination at clinician and patient level. Clinicians had a low number of participants to treat each, making it hard for them to generalise their experiences. No ethnicity data was collected. All three study sites were in the North-East of England in areas with high levels of deprivation and may not be representative of other areas of the UK. Attempts to minimise loss to follow-up were ineffective.

According to the Cochrane Collaboration's tool for assessing risk of bias (Higgins et al., 2011), this study risks reporting bias (as there was no pre-published protocol) and an unplanned analysis was conducted for the purposes of this thesis. Attrition bias was present due to incomplete outcome data although we have attempted to account for this in the exploratory analyses using multiple imputation and LOCF within an ITT analysis. However all exclusions and attrition were reported and all randomised participants were accounted for. There was also a high risk in

relation to no blinding of outcome assessment, which could lead to detection bias and no blinding of participants or personnel could lead to performance bias.

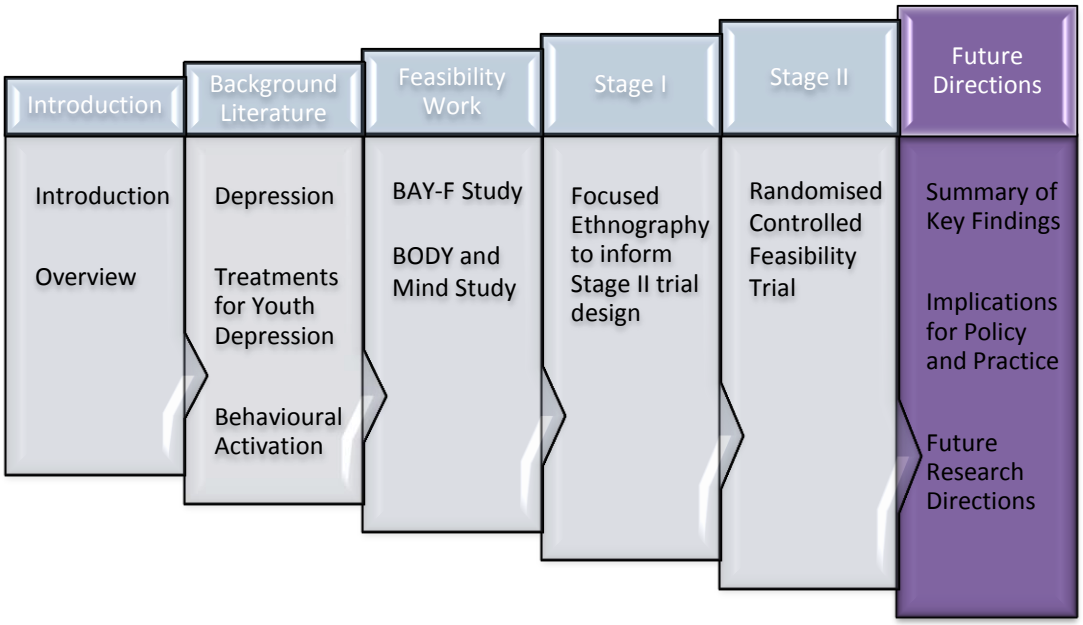
Conclusions

This study adds to the literature on BA treatment in the UK. A BA manualised intervention for the treatment of young people in CAMHS with depression has the potential to represent an effective and acceptable solution to address the significant unmet need in provision of psychological support. If a larger fully powered trial were to show BA was comparable or non-inferior to CBT, as has been shown in adults (Richards et al., 2016), it would have substantial implications for practice.

As in all treatments, and as observed in previous pilot studies of the application of BA to young people (Ritschel et al., 2016), we did not find BA was suitable for all participants. The key learning is the need for flexibility in delivering this novel treatment whilst considering the restrictions imposed by the service. The qualitative interviews enabled understanding on how staff adapted the manualised treatment into practice, sometimes in unanticipated ways, in order to deliver it in their local context.

We were able to successfully recruit staff from, and adolescents attending, routine CAMHS. Broadly speaking, the qualitative results were encouraging from young people and their families but the feedback from staff about their participation in the study suggests caution. The findings are limited by attrition (particularly at 6-months) and inherent biases, as a result of the study design. The BUDDY study suggests that a trial of BA for young people with depression may be feasible in an adolescent mental health setting. Moreover, there are at least tentative suggestions

that, compared to TAU, the BA approach may be more effective. Therefore, BA as a potential evidence-based treatment for young people with depression warrants further research in order to adequately address some of the outstanding feasibility questions.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Chapter 5 Thesis Summary

Two intricate studies have been undertaken to address the aim of exploring the feasibility of conducting a trial of a Behavioural Activation (BA) intervention in a UK Child and Adolescent Mental Health Service (CAMHS) setting. The final chapter starts by detailing the main findings of this body of work, followed by a discussion of the implications of the research, the dissemination plan and proposed future research directions.

Main Highlighted Findings

- The focused ethnographic methodology was flexible and sensitive to the social context of the study site. This rigorous approach to data generation led to Stage I of the research successfully informing the design of the subsequent trial in Stage II.
- Recruitment of participants to the feasibility trial in Stage II was successful, but could be further refined by removing researcher-led recruitment methods.
- Trial participants were complex and multi-morbid, reflecting the setting, which increases the relevance of the findings for clinical services and policy makers.
- Recruitment and retention of staff to Stage II of the research was successful. The BA treatment was disseminated to lower-grade CAMHS staff, who were able to deliver the brief intervention after receiving four

days training. Although, fidelity to the BA model was unable to be assessed.

- The study procedures in Stage II of the research were acceptable to the adolescents and their families. Usual care was viewed as an appropriate comparator and young people tolerated randomisation well.
- Most staff reported a variety of positive aspects of BA treatment and highlighted its utility in reducing symptoms of depression. However, one staff member found that BA treatment was incompatible with her usual eclectic practice. For others, there were caveats in relation to delivering the BA treatment using a structured manual and a lack of consensus over whether BA should be delivered as a 'stand-alone' therapy or deployed alongside other evidence-based treatments. These outstanding feasibility questions should be explored in future research.
- The BA intervention format and content was acceptable to the involved young people and their families. Most young people experienced positive outcomes in terms of their depression, low mood and self-esteem. Young people particularly valued working collaboratively with their therapist and goal-setting activities. However, some young people and their parents experienced barriers to fully engaging in BA treatment. The key message was ensuring treatment is adapted to the individual.
- The findings of this research add further to support the developmental approach to research data generation as advised by the Medical Research Council (MRC), as without the preparatory work undertaken, resources within the trial would have been wasted.

- The trial completed in Stage II of this thesis represents the first UK-based randomised study of a BA intervention for young people with depression in secondary care. As such, the Behavioural Activation for Major Depressive Disorder in Youth (BUDDY) study offers important insights into conducting a trial of a brief BA intervention in a UK CAMHS setting. A further strength was the use of a formal qualitative methodology to explore the experiences of adolescents, their parents and clinicians in relation to the BA intervention, which has advanced the international literature.

Implications of the Findings

A recent systematic review (Tindall et al., 2017) identified ten studies of BA treatment for depression in young people; none were UK-based and only three were Randomised Controlled Trials (RCTs). Since then, there has been one further RCT, in the USA, published in the area. All published UK-based evidence to date is based upon case study designs (Pass et al., 2015, Pass et al., 2016, Pass et al., 2017) and although this simple observational approach can be useful, as discussed in the background literature chapter, it is prone to bias. Internationally, few of these studies employ randomisation, which is an important control to reduce bias. As such, the BUDDY study will add to the growing international literature for the utility of a BA approach to treating depression in an adolescent population. Although the studies included in this thesis provide new and interesting knowledge about delivering complex interventions in a CAMHS setting, the results only provide provisional and early indications that BA may be a plausible treatment. The most

central findings relate to the learning gained around integrating a RCT of this intervention into a complex setting. This data will inform future research in this area, specifically by highlighting valuable areas for future studies to focus upon.

The novel focused ethnography stretched the paradigm to inform the planned trial. Uniquely, the BUDDY study contained both randomisation and a significant qualitative arm, which explored the utility of the approach with both young people, their families and their clinicians. These qualitative findings in particular, potentially challenge the feasibility of BA delivery in a UK CAMHS context. It would be pertinent to explore the impact of staff's clinical backgrounds on the delivery of psychotherapy, in light of the findings of the BUDDY study, as this may limit the clinical utility and generalisability of the BA approach in CAMHS teams. Other clinicians questioned the rigid and prescriptive nature of the manual and the impact this has on therapeutic alliance. Staff noted lacking the flexibility to respond to emerging issues during treatment may hamper patient care. This is a crucial question when services are attempting to cut costs and standardise treatments.

The results from the BUDDY study are consistent with the majority of available studies in the area, in that we have found provisionally positive indications for BA as a treatment for depression in young people. The one case study that reported less favourable results was an early investigation using the 'Adolescents Taking Action' (ATA) manual (McCauley et al., 2011). However, following the adaptions made to the manual following delivery to this individual a large RCT using the manual did not report further difficulties. The results of the BUDDY study will inform the direction of future research and support existing calls for further research in this area. The focus of future directions will be discussed in more detail below.

Implications for Policy and Practice

Child and adolescent mental health sits at the centre of the NHS Five Year Forward View (Ham and Murray, 2015, Department of Health, 2014). Currently in CAMHS, the demand for specialist mental health treatment outstrips the services' capacity to provide it. The Department of Health states the need for early and effective evidence-based treatment available to those young people who need it (Department of Health, 2013a). As detailed in the background literature chapter, current evidence-based treatments for depression are costly to train staff in and resource intense to deliver, both in terms of the number of sessions required and the level of staff experience to deliver existing treatments. Successful delivery of such treatments requires extensive staff training and intensive, resource heavy packages of care, typically requiring a large number of treatment sessions. This may be incongruous with the NHS climate of austerity where difficult comprises have to be made. In Stage I of this thesis, the difficult compromises the service had to make in light of this lack of capacity were alluded to. Encouragingly, my work has the potential to inform the future provision of equitable and effective care for adolescents.

As discussed above, there is a lack of research evaluating BA in a UK-setting. Conducting research in a UK setting was particularly important because of the differences in the way healthcare is funded in the UK and the primarily insurance-driven US. The Child and Young Person's Improving Access to Psychological Therapies (CYP IAPT) programme aims to provide evidence-based therapy to young people and BA represents a plausible alternative to more costly, timely and complicated alternatives, such as Cognitive Behavioural Therapy (CBT). As National Institute for

Health and Care Excellence (NICE) guidance currently does not recommend BA as a standalone treatment for youth depression (National Institute for Health and Clinical Excellence, 2005), understanding how BA can be applied in a UK setting offers the opportunity to influence policy and practice, and inform future guidelines. The research detailed in this thesis and the proposed future research directions discussed below have been designed to be sensitive to policy maker's requirements for high quality evidence to support clinical decision-making. In the BUDDY study and planned future trial, clinically relevant alternative interventions have been selected, the trials include a diverse population of participants recruited from clinical practice (and relatively representative of a CAMHS population), and data are collected on a wide range of health outcomes. Reliable evidence is required to support efficient use of limited resources and this is particularly the case in a CAMHS setting (Tunis et al., 2003) and in times of economic constraint.

One unanticipated outcome of this research was a greater understanding of the pathways participants took through CAMHS services' Treatment As Usual (TAU). Although there were positive journeys these were in the minority, with most young people receiving little active treatment in the control arm of the study. This extends the debate and has wider resonance in conveying a message to commissioners and practitioners alike that new approaches to providing treatment within overburdened services is essential and timely. One hope in conducting and completing this research was, in some small way, to help to improve CAMHS services. There are many learning points from this research, although few offer solutions or positive messages. Within the qualitative strand of the BUDDY study, staff reported that a manualised approach to treatment may affect their therapeutic relationships; in contrast,

families were positive about this aspect of their BA treatment. These disparities need to be explored further before the findings would give credence to the suggestion that a manualised treatment could be a way forward to address the identified shortfalls in CAMHS care.

Dissemination

According to the MRC, dissemination is a central part of the research process (Craig et al., 2008) and is also an ethical obligation for researchers. Consequently, writing publications from my PhD research is a key priority. Stage I of this research (the focused ethnography) has already been published in *Trials*, an open-access journal, as a case study for the innovative approach taken to sequencing mixed methods in the context of trial design (Kitchen et al., 2017). The next planned publication is a short report to provide an overview of the RCT results of Stage II of the research, which will be submitted for publication in an academic peer-reviewed journal. Although underpowered tests have been performed for the purposes of the thesis, these will not be reported when seeking publication. Following this, a mixed methods paper will explore the RCT findings in more depth. It is anticipated that this will present challenges in conveying the complex findings in a meaningful format within the limitations of an academic journal.

A lay summary of the study results was sent to participants and their families in November 2017 (see Appendix 13). The next priority is further dissemination activities to academic and non-academic audiences. The results will be presented at academic conferences and via local University and Trust presentations during 2018/19. This will include presentations to the participating CAMHS teams. The

research will also be written in an accessible format for 'The Conversation', a blog-site featuring academic and research news, which reaches monthly audiences of 5 million readers. In addition, funding has been sought for further innovative, youth-led dissemination activities.

Future research directions

The research conducted as part of this thesis identified many prospective avenues for further research. In the section below, two of these key domains are discussed, including a description of each overlapping area and why they may be worthy of further investigation.

Clinician characteristics and the delivery of psychotherapies

My PhD research raised some challenging questions about the way in which psychotherapies are delivered to young people in a CAMHS context. The first proposed area for future investigation relates to an issue identified in both stages of my research, related to the professional backgrounds and skillsets of staff who are trained via the CYP IAPT Programme and the individual factors that may impact upon the delivery of psychotherapy in this context. Findings of unexplained variability in clinical practice, high rates of inappropriate care and increased care costs have led to an increased demand for evidence of clinical effectiveness (Tunis et al., 2003). It may be that clinical effectiveness needs to be considered more broadly, rather than with a narrow focus on the effectiveness of the intervention of interest. Future research could investigate the feasibility of using existing CYP IAPT data from the national Mental Health Services Data Set, to explore the individual qualities that result in mental health professionals being more effective at engaging young people in

psychotherapies delivered in CAMHS and how these factors may relate to patient outcomes. Understanding these features is important in ensuring that CYP IAPT is effectively delivering evidence-based training and enabling practitioners to provide evidence-based treatment. It is also vital to understand what type of professionals may be best suited to delivering certain interventions because it would assist researchers and policy makers in recognising how best to generalise the results of the BUDDY study and future research more widely (to youth workers for example) to help improve wellbeing.

Future trial of behavioural activation for young people with depression

The promising findings relayed in this thesis have provided evidence that BA warrants further investigation as a treatment for depression for young people in CAMHS. The next step, based on these preliminary findings, is to plan a larger phase II (pilot) randomised trial to examine methodological and procedural uncertainties in a more rigorous manner (Craig et al., 2008). Pilot studies are miniature versions of the main study (O'Cathain et al., 2014). Subsequent progression of this research programme would then lead to a possible future definitive (phase III) RCT (informed by the results from the piloting phase). A fully-powered (phase III), well-designed RCT evaluating an intervention provides strong evidence of a cause-effect relationship if one exists (Kendall, 2003, Thabane et al., 2010). As such, a large, well-designed RCT would contribute much needed quality evidence to the field of BA as an intervention for depression in young people. However, due to the outstanding feasibility issues identified during the BUDDY study, the next logical step would be to conduct a pilot, rather than a definitive trial. As per the MRC guidance for complex

interventions (Craig et al., 2008), an intervention should not progress beyond the piloting or feasibility stage if questions relating to feasibility have not yet been answered. Based on the BUDDY study results, we cannot yet be confident that the intervention can be delivered as intended due to outstanding questions that remain about fidelity, the manualised format of the treatment and the mode of delivery within the service. This is in keeping with MRC guidance that suggests depending upon the results, a series of pilot studies may be required to progressively refine the trial design before embarking on the definitive trial itself (Craig et al., 2008). The purpose of a pilot trial is to conduct a definitive trial in miniature (National Institute for Health and Clinical Excellence, 2017). There are two commonly touted alternatives when designing a pilot trial; an internal or an external pilot. An external pilot study is where the pilot trial is conducted independently of the definitive trial and, if the results are promising, further funding is sought for the fully-powered trial at a later date. The benefit of this approach is that resources are not wasted planning a larger trial that may have to change following the results of the pilot or may not be feasible at all. However, although according to the MRC, piloting and feasibility are viewed as integrated activities (Craig et al., 2008), the NIHR Research for Patient Benefit funding stream does not fund independent pilot studies as they are viewed as part of a phased development of a full trial (National Institute for Health Research, 2017). In contrast, as the name suggests, an internal pilot is situated within a planned definitive trial (Lancaster et al., 2004). Criteria are pre-determined to progress from the pilot phase into the definitive trial, but this approach has been criticised for restricting the opportunity for significant changes in the trial design and it can lead to an increased risk of type I errors if the pilot data is

included in the final analysis, as the two trials are being treated as unrelated in the sample size calculations (Lancaster et al., 2004). In light of the scope of the aforementioned outstanding feasibility questions from the BUDDY study, which may require significant changes to the protocol, an external pilot may be the most appropriate future study design.

Key considerations are outlined below, in relation to deciding upon the methods to be used in a future pilot study to address the feasibility trial limitations. Sources of potential bias and remaining uncertainty about the feasibility of BA as a treatment for depression in CAMHS are discussed.

Consent and recruitment procedures

The consent procedure involving young people aged 16-17 providing informed consent or parents/carers (of patients under 16) providing informed consent, alongside their young person's informed assent worked well in the BUDDY study. The age-appropriate materials informed by Patient and Public Involvement (PPI) were also acceptable to families. A similar procedure could be utilised in future trials. However, one concern was the lack of knowledge the young people in the BUDDY study had about the treatment options they were being offered. This suggests the need for more innovative strategies to adequately inform young people and their families about their care options. This is particularly challenging in trials that use a pragmatic comparator condition, such as usual care, because it is not possible to describe the exact treatment these participants will be offered.

Trial design, randomisation and blinding

In the BUDDY study, the BA staff at each site may have been a source of contamination as they regularly encountered other members of the team and

discussed the treatment of their patients. The findings from the focused ethnography of the CAMHS site, observed informal learning between team members rather than this being restricted to formal training or supervision sessions. The planned fidelity assessment may have provided an indication of whether therapeutic contamination was the case, whether this was from BA into the TAU arm or vice versa. However, this was unable to be commented upon in the BUDDY study due to a failure to collect audio recordings. The reasons why recordings were not made by clinicians as planned should be explored at an early stage of a future trial, in order to overcome these obstacles. If contamination was found to be occurring in a future pilot study, the trial design may need to be altered to account for this. One option would be a 'cluster' trial where groups of individuals or sites (such as a CAMHS team) are randomised to treatment as a whole. However, cluster randomised trials are inefficient, in a statistical sense, due to a lack of independence and therefore a large sample size is required to account for this (Everitt and Wessely, 2008). In terms of the pilot trial, a conventional individually-randomised parallel group design would be preferable and could be reconsidered if treatment contamination was observed.

In the BUDDY study we utilised blocked randomisation, which was conducted by an otherwise uninvolved statistician. An independent statistician is an important control against bias; however, in a future trial the block sizes should be larger and randomly mixed in size to reduce the possibility of being predicted. This is important as predictability conflicts with the principle of randomisation (Kim and Skin, 2014). Although we used remote telephone randomisation in the BUDDY study, we used non-specialists to staff the service who did not have access to specialist randomisation software. Due to this, it was possible for the secretary to see the next

allocation on the randomisation list, which is a potential source of bias. It is therefore advisable to delegate specialist tasks to those who have appropriate expertise and resources (Kendall, 2003). In future trials, a professional remote randomisation service should be used where staff are blinded to the next allocation.

A double blind study is the recommended design for RCTs whereby both investigators and patients are blinded to the treatment allocation, where this is not feasible it is advised that a blinded third party should be responsible for the collection of outcome measures (Kendall, 2003). It is also important to note anyone who is unmasked to treatment allocation during the trial.

Treatment Manual

During the BUDDY study, the ATA BA manual and associated materials represented a barrier to engagement in treatment for both young people and their clinicians. As discussed in the previous chapter, changes to the format and delivery of the manual have been suggested. Clinicians were vocal about their difficulties with the number of worksheets for each session, which made it difficult to deliver the treatment within the prescribed timescale. This suggests the manual requires further refinement prior to a pilot study. One method for investigating this further would be a formal usability method such as a 'think aloud' technique, which has been utilised in other studies of BA. In America, researchers video-recorded 24 adolescents undergoing a BA computerised module whilst voicing their thoughts on the BA programme (Davidson et al., 2014). The purpose of this additional qualitative research would be to assess the satisfaction of young people, their families and clinicians with any changes that would be made to the ATA manual. This would be a way to capture practice wisdom from clinicians and purview from young people's

experiences using the materials in the context in which they are to be deployed. Webber (2014) discusses how involving clinicians in the creation of such materials provides external validity and 'currency' with practitioners due to the materials resonating with staff.

Manualised treatments have become attractive to commissioners and services with reduced budgets who are required to deliver evidence-based treatments (Olubokun, 2017). The theoretical advantage of a manualised approach is consistency across treatment sessions and facilitation of the internal validity of the data by minimising the impact of the therapist on outcomes (Olubokun, 2017). Poor adherence to the protocol and feedback on therapist effects from the BUDDY study would suggest that a manual may not be feasible in this setting or that it requires further adaptation. In Rutter's opinion, however, rather than fidelity or adherence, it is in fact the skill or competence of the practitioner in deploying the manual that is more relevant. Olubokun (2017) reported manuals can be criticised for being too rigid, regimented and inflexible, taking the approach that "one cap fits all" or not reflecting the real world of clinical practice. This was stated explicitly by one clinician in the BUDDY study, and other staff made reference to this when reflecting upon the manual use.

There were suggestions that the ATA manual was not flexible enough to address young people's comorbid mental health difficulties, such as anxiety. Some staff also felt the manual did not enable them to adequately tailor the BA treatment to each individual. Although the current ATA manual ensures all topics are covered in a logical order, greater emphasis needs to be on the flexibility for the practitioner to adapt the manual delivery to aid patient learning and engagement. In the pragmatic

ADAPT trial of CBT in adolescents with depression, the manual content was used only as a guide to ensure the principles of treatment could easily be incorporated into NHS practice rather than rigid session by session instructions (Goodyer et al., 2008). Another option to address this is to have optional modules within the manual itself. There is some debate about the utility of a 'modular' or 'linear' approach to manualised treatment, and which approach is most useful (Rutter et al., 2008) (Rutter et al., 2008). In a linear sequenced manual, all sessions have to be covered before treatment is complete, whereas in a modular manual there is more flexible in terms of the number and order of treatment sessions (Rutter et al., 2008). A modular manual may meet clinician's desire for greater flexibility during BA treatment. However, previous research suggests that a modular approach may not be a good fit for a BA manual (Weersing et al., 2008) as a modular manual indicates a comprehensive approach is being taken to treatment whereas in BA there is a higher value placed upon parsimony. The concept of modular verses linear manual design could be explored via PPI with stakeholders in advance of a planned pilot study and could then be evaluated during the trial.

Further to this, some staff members reported that delivery with a manual per say was incompatible with their usual delivery of care for depression. This is a potentially insurmountable feasibility issue in terms of the current BA delivery format that needs to be explored in further detail prior to or during any proposed pilot trial. A qualitative methodology is most likely to be useful to further illuminate practitioner's experiences of using manuals to deliver psychotherapy in CAMHS. Wells et al. (2012) also found that staff developed their own ideas and preferences in relation to implementing treatment using a manual, but was unable to adequately

capture this knowledge due to the limitations of a traditional RCT design. It may be, in line with previous research (McCauley et al., 2016), that once BA strategies have been more thoroughly evaluated in young people they may be most useful as a first option in a stepped model of care or as components in a modular approach to the treatment of depression, allowing the therapist to follow an eclectic mix of evidence based therapies.

In line with participant and parental feedback during the qualitative interview in the BUDDY study, another suggestion for a future trial would be the inclusion of 'top-up' sessions or staggered delivery in the final BA sessions. The advantage of a top-up session is that it allows the young person to focus upon a topic of their choice and grants practitioners greater flexibility. This approach has been used in later iterations of the ATA manual when delivering BA to young people (McCauley et al., 2016).

Mixed Methods

Although the information gleaned from the qualitative interviews was informative, young people, their parents and clinicians had to condense many months learning and experiences into a one hour interview. This may have meant vital information was lost. Multiple interviews over the course of treatment, reflexive diaries or recordings may be useful to counter this limitation during the trial. This is in keeping with a review by Lewin (2009) that suggested current RCT designs are not optimising the integration of qualitative research and that this is vital to better understand the effects of interventions and how they are experienced by those participating in the trial. The continuation of a mixed methods approach, particularly the extension of the qualitative element of the feasibility study into the external pilot to explore

participant's views on the changes to the intervention and data collection methods would be valuable. This would be in line with the MRC Guidance that recommends implementing a process evaluation to help to explain discrepancies between expected and observed outcomes (Craig et al., 2008). The impact of this design decision needs to be considered, as it can have broad consequences for the trial research team as a whole. O'Cathain et al (2015) describe three models of the relationship between qualitative research and a trial, based upon a qualitative study of researchers. The first is the 'peripheral' where the intention of qualitative research is not to add value to the trial but for another purpose (i.e. as an opportunity to obtain a higher degree). The second is the 'add on' where the qualitative researcher believes in the value of qualitative research but this belief is not shared by the lead investigator or key team members and third where qualitative research is viewed as 'integral' essential to evaluation. The resources required to undertake a qualitative evaluation should only be expended if it is integral to the study as a whole, or else the qualitative research risks becoming tokenistic.

In the pilot trial design, I would argue for continuation of the ethnography throughout the trial stage of the study. The rationale for this is that it enables observation of the implementation of the research and the intervention in context; viewing the trial findings in a holistic way. However, the very recognition of context may challenge the central tenants of RCTs (Wells et al., 2012). The MRC recommends that a mixture of qualitative and quantitative methods are needed, for example to understand barriers to participation and to estimate response rates (Craig et al., 2008). Previous research has utilised ethnography alongside RCTs (Ananthpur et al., 2014), this approach will aid balancing a robust qualitative approach with a

pragmatic stance. Ethnography can indicate why an intervention did or did not work, enabling amendments to the trial protocol to be made (Savage, 2000). Document analysis may be a useful tool in order to place the BA intervention within a broader policy context using local and national policy documents. For example, relating to the observed Tier 2 eight-session treatment limit. Observational fieldwork would also inform the subsequent intervention; offering a staff viewpoint from the wider team that would be otherwise inaccessible. These methods will be particularly informative in respect to how the trial may be perceived in an organisational context. A significant limitation is the cost of completing an ethnography; although these are reduced using a focused approach, they may still be prohibitive. Traditional ethnographies may also encounter difficulties repeatedly securing access to the site (Reeves et al., 2008), especially when difficult findings are uncovered. As suggested in Stage I, engagement with gatekeepers is crucial in this respect. Another avenue to explore would be the use of 'combinative' fieldwork, where fieldwork is conducted simultaneously in different sites (Webber, 2014), accounting for different practice contexts with the aim of facilitating smooth implementation of the trial or intervention. However, the benefits of increased qualitative components of a trial need to be weighed against the potential for them to become an intervention themselves (O'Cathain et al., 2015). In the BUDDY study, the qualitative interview was conducted prior to the main outcome measures, which may influence the later outcomes taken and could represent a source of bias. This was particularly so in the BUDDY study where the qualitative interview was only offered to those in the BA arm. In future trials this could be countered by completing the interview following the follow-up assessment and offering the interview to participants in both arms of

the trial. As recommended by the MRC, a process evaluation marries well alongside a pragmatic trial. The importance of trials including multiple methods, sources and perspectives has been highlighted as a way to ensure they adequately reflect the context of clinical practice (Wells et al., 2012).

Data Collection and Treatment Delivery

During the BUDDY study, patient characteristics and treatment data were not recorded on the patient electronic records system in a systematic way by staff, which meant information relating to ethnicity, diagnosis or treatment content was unable to be obtained. A standard template requesting this information at baseline and during treatment sessions could account for this in a future trial, as used in the ADAPT trial (Goodyer et al., 2008). Although this represents a source of additional staff study burden, this information is vital due to the known high placebo response rate in depressed populations. Therefore, placebo-controlled studies are essential to determine whether any changes are due to therapeutic effect rather than just the fact the participants have had more therapeutic contact (Merry and Stasiak, 2012). This represents a confounding variable that should be controlled for in future studies, as even when using an active control such as TAU, if the session content or length is not known, it is impossible to separate the impact from contact time with a clinician from other treatment effects. By accurately recording this information aspects, such as the number of treatment sessions, can be controlled for using statistical techniques in a larger future trial.

Another related difficulty in the BUDDY study was that staff in the TAU arm were not asked to follow a standard treatment manual or given specific guidelines such that the quality, quantity and content of the intervention could not be assessed

or controlled for. A comprehensive treatment protocol should be used; this could be situated within the setting by developing this protocol with stakeholders via PPI prior to the start of the trial. This will need to be reappraised in light of the findings from staff in relation to the utility of the BA manual. In the Improving Mood with Psychoanalytic and Cognitive Therapies (IMPACT) study they justify the use of manualised treatment based upon three points (Goodyer et al., 2017): firstly, protocols aid dissemination of treatment methods into clinical practice and aid standardisation of the intervention between therapists and across sites. Finally, the protocol can be used as the basis of assessment for fidelity ratings during treatment delivery in both arms of the trial. This, they argue, ensures that the interventions have been given appropriately and perhaps most importantly, that therapists in the group do not give the other intervention.

Outcome measures

In the BUDDY study, not all deployed outcome measures were successful. The BADS was difficult for young people to complete, and is not validated in this population. As such, an alternative more youth-friendly measure of activation or activity should be trialled in future studies following PPI input.

Continuous outcome variables have the benefit of increasing the power of the trial over dichotomous variables (such as a diagnosis of depression using the Kiddie-SADS-Present and Lifetime Version) with only two outcomes (depressed/not depressed), which in turn permits a smaller sample size (Kendall, 2003). Therefore, the primary outcome measure in a future pilot study should be the Mood and Feelings Questionnaire- Child Version.

One major threat to the validity of the BUDDY study was the low follow-up rate at three-months and the very low follow-up rate at six-months. One reason to account for this is the high rates of drop-out in the CAMHS service as a whole, though there were also some suggestions that the setting for follow-up appointments may not have been optimal for all participants. One family fed back that due to dropping out of the service they did not want to return to the building and I did not have ethical approval to conduct follow-up interviews at home. Young people in a previous consultation suggested home visits would be appropriate to reduce anxiety (Affleck and Seed, 2015). To accommodate this, future research should offer more flexibility in terms of the location of follow-up appointments.

Pilot Trial Summary

Although this chapter did not provide an exhaustive list of issues to be considered when designing a future pilot trial, it intended to summarise the learning gained from the BUDDY study and how findings could be utilised when planning future research. To summarise, a future pilot trial should include an adapted manual, mixed methods, research assessors independent of the treatment team and blind to randomisation, analysis by ITT and treatment protocols in both arms.

Personal learning

I feel I have learnt an immense amount whilst researching for my PhD. The core of that learning consisted of the research, writing and management skills that I have gained but, in this section I also wanted to reflect upon the more personal impact of studying towards a PhD. As someone who has never considered themselves, nor was I considered to be, academic at school, a doctorate was never an aspiration. I think

this led me to view my PhD very much as a practical apprenticeship that represented a route in life that I expected I would follow. As such, I sought out practical opportunities to learn along the way. The chance to undertake a clinical psychology placement alongside my PhD allowed me to expand my interests (after studying psychology at undergraduate level) and offered insight into the clinical population that I was studying, a chance that would never usually be afforded in a purely research-based PhD. Initially I did not fully appreciate the importance of this, but over the course of the two-year placement, I realised how the exposure to the setting from my role as an Assistant Psychologist was shaping my approach to research, the staff on my placement, my participants and to life in general. I naively thought that the writing or the statistics would be the areas of my PhD that would stretch or challenge me the most. Of course, I was wrong. These quickly became insignificant whilst on my clinical placement and during the data collection for Stage II of the study. The harrowing stories that families shared with me, especially the articulate descriptions the young people gave of their struggles, gave me a strong dose of perspective. I found dealing with clinical risk particularly difficult. Those stories will stay with me forever and remind me that any stress encountered during the process of creating this thesis should be remembered in the context in which it was created.

Another opportunity I sought during my PhD was to obtain funding from the British Psychological Society to undertake a three-month secondment to work in the Parliamentary Office of Science and Technology in the Houses of Parliament. This experience highlighted gaps in my knowledge in terms of policy and research impact. I was able to observe the process of how research feeds into policy, and ultimately

practice. These experiences have confirmed my desire to work in applied health research, rather than a theoretical area.

Entwined with the emotional struggle, I encountered other challenges such as finding my 'authorial voice' as mentioned previously. My friends and family would find this surprising for someone who doesn't struggle to articulate their views in everyday life; I think in the context of my research it was a case of imposter syndrome and a lack of confidence in my own ability to draw something meaningful from my data. I particularly liked Mason's (2002) advice of being an active participant in qualitative research enquiry, rather than a passive researcher following a recipe book. However, my natural affinity to follow instructions made this self-directed inquiry difficult for me initially. In this respect, my supervisors have had a profound influence on me. Like my Stage I participants, my supervisors came from a variety of backgrounds; a psychiatrist, a nurse and an anthropologist. As is often the case, varied backgrounds lead to varied viewpoints, which offered invaluable perspectives that became an amazing resource during my PhD; although, on occasion, it was difficult to find a balance between my own knowledge gained from the setting and my supervisors' personal experiences. Dikotomis (2016) reflects on the 'academic world view' and the comfortable environment of working with others who share this view. My diverse supervisory team led to an ongoing dialogue about ethnographic writing. I hope that I used these varied influences as a platform to explore, investigate and inform my own opinions that are presented in this thesis. Although my background is in psychology, I found increasingly during the course of my PhD that my research sat on the intersection between psychology, health, medicine and anthropology. Alongside this, my mixed methods approach to trial design meant that

I also didn't fit neatly into the primarily quantitative trials tradition. Working at the interface of different disciplines, departments within the university and different methods has led to challenges articulating where to situate myself and my research. The methodological expertise within my own supervisory team was disparate; a trialist, a qualitative researcher and a psychometrician; all of whom brought with them different expertise. This was never more so evident in discussions relating to theory and pragmatics reflecting the wider disciplinary disputes. Whilst providing a vital resource upon which I capitalised, these diverse sources of oversight sometimes made it difficult to form a path of my own making. I can't help but reflect that this echoed the difficulties observed in the CAMHS team.

The primary gain from the process of producing this thesis is the opportunity to reflect upon the learning and experience I have gained in mixing methods. The initial decision to mix methods was established due to a desire to capitalise on the advantages of both approaches. The results and experience of the trial has enabled me to evaluate these decisions more critically and has provided time to reflect upon both the combination of the different methods selected and the sequencing of those methods. This insight is not often obtained because in larger trials, experts in quantitative and qualitative methodologists are often asked to consult upon their own area of expertise, which leaves the trial without an overarching methodologist. This makes it difficult to fully appreciate the challenges of mixing methods and leads to what have been termed 'paradigm warriors' (Kelle, 2006), where researchers assign themselves to a particular approach and offer unhelpful critical appraisal of other approaches, making it difficult to adopt a constructively critical view of their own tradition. I argue towards a more unified approach that acknowledges the pros

and cons of each approach, with a particular attention towards the issues arising when these often disparate approaches are mixed. Barbour (2014) opts for not categorising specific types of mixing methods, in contrast to Creswell (2007), in order to encourage innovation and thoughtful mixing of methods. Typically, mixed methods occur, as in this study, at an exploratory stage of a trial. The results of this research suggest there could be many advantages to extending this approach throughout the trial phases. I hope to publish my findings in the mixed methods format that I intended.

Conclusions

The results of this research are complex and multi-faceted, much like the setting in which the research was situated. The previous preparatory work, the focused ethnography of the study site and the pragmatic trial design removed common obstacles to study and intervention implementation during Stage II of the research.

As would be expected however, the implementation of a complex intervention has met barriers that need to be further be explored, particularly in relation to staff's experiences of delivering the BA intervention in a manualised format and the integration of the treatment into usual clinical practice. Although it may seem that this research has generated as many questions as it has answered, it has furthered the research field in the UK, added to the growing literature internationally for the utility of a BA approach to treating depression in an adolescent population. Furthermore, it has facilitated the ongoing adaption of the intervention in order to prepare for a larger definitive trial of BA as a brief

intervention for depression in young people in CAMHS. The findings support the case for future studies evaluating BA in this setting.

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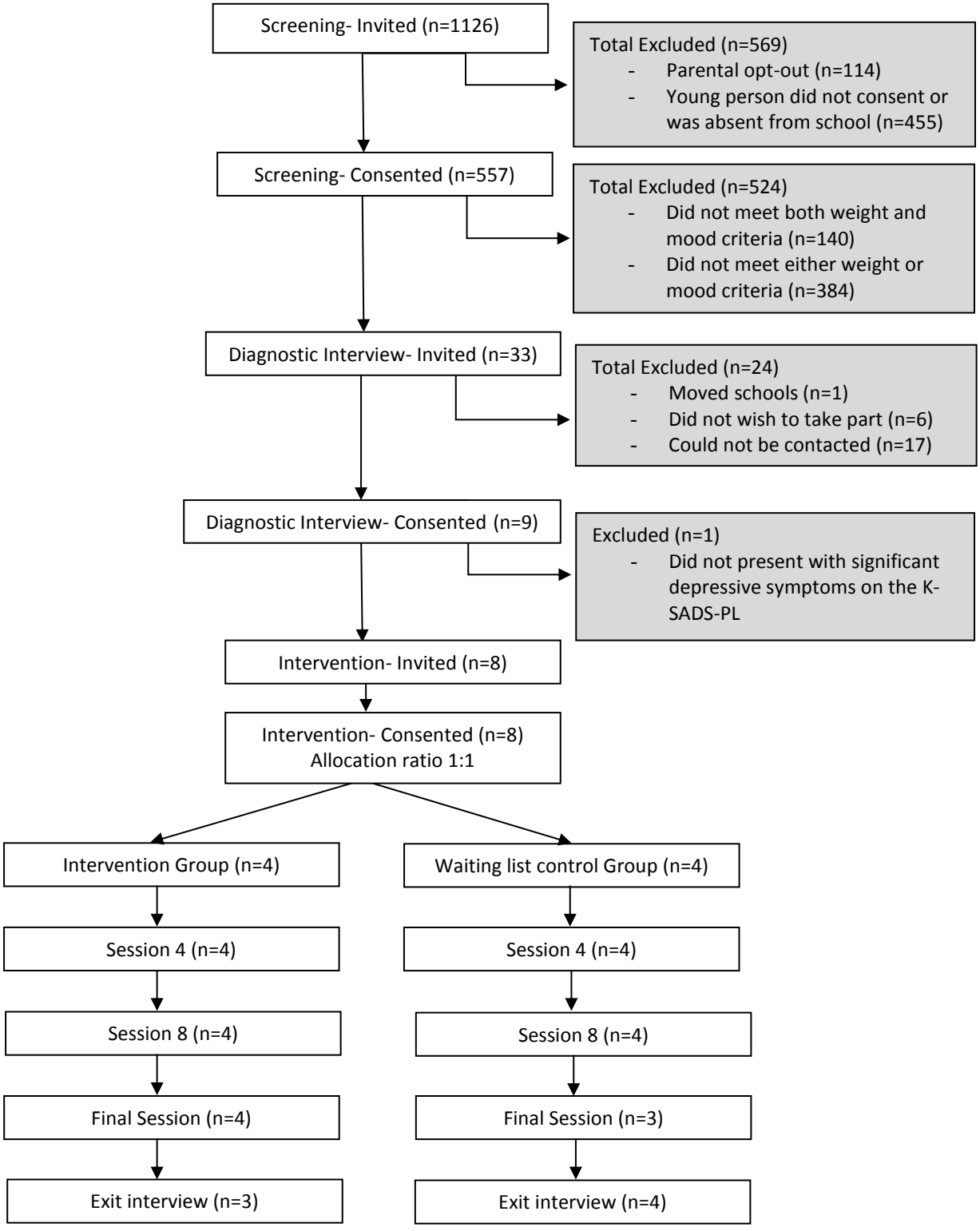
Appendix

Appendix 1

BODY and Mind Study: CONSORT flowchart of participant recruitment and retention



BODY and Mind Study: Qualitative Themes

Theme	Description
Pressure	This theme was rooted in the screening element of the study where young people felt peer, school and parental pressure to participate. In some respects, participants felt under pressure to take part and in other ways, they felt pressured to withdraw. It also incorporated participant's concerns that they may 'fail' the screening tool.
Stigma	This encapsulated families' negative perceptions of treatments for mood disorders, stigma around being overweight and gender differences in this respect. This included the experience of being identified to participate in the study, which led to varied reactions ranging from feeling special to being nervous. Participants valued the confidentiality the sessions offered with a facilitator from outside of the school setting. However, the location for these sessions was not universally popular.
Responsibility	This aspect was key to families' experiences throughout the study. Participants valued the opportunity for self-recognition of their mood/weight problems and they emphasised their role in maintaining these difficulties. Young people would have preferred more control over the level of parental involvement in their treatment. However, they appreciated the self-directed nature of treatment and working together with the therapist to achieve their goals. Those that reported longer-term improvements attributed this to their increased motivation to change their lifestyle. Those who did not experience any impact upon their life from the treatment blamed external barriers, such as their parents/carers.

Appendix 2

Stage I: Ethical Approval from the School of Medicine, Pharmacy and Health Ethics Sub-Committee

Durham University
School of Medicine, Pharmacy and Health

Shaped by the past, creating the future

Dr David Ekers
Clinical Senior Lecturer
Chair, School of Medicine, Pharmacy and Health Ethics Sub-Committee

Charlotte Kitchen
School of Medicine, Pharmacy and Health
Durham University

4th September 2014

Dear Charlotte,

Re: Ethics Application ESC2/2014/06
A focused ethnography of a Child and Adolescent Mental Health Service to inform the design of a randomised controlled trial.

Thank you for sending the above application to the School of Medicine, Pharmacy and Health Ethics Sub-Committee for ethical review. The project was reviewed at a meeting on 25th June 2014. The committee requested some changes to the application, and I have now reviewed these as Chair. I am satisfied that all of the comments made by the committee have been addressed and I am therefore pleased to confirm Durham University ethical approval for the study.

This approval is given on the following basis:

- Please ensure that data generated for this study is maintained and destroyed as outlined in this proposal and in keeping with the Data Protection Act.
- If you make any amendments to your study, these must be approved by the School committee prior to implementation.
- At the end of the study, please submit a short end of study report (ESC3 form) to the School ethics committee.

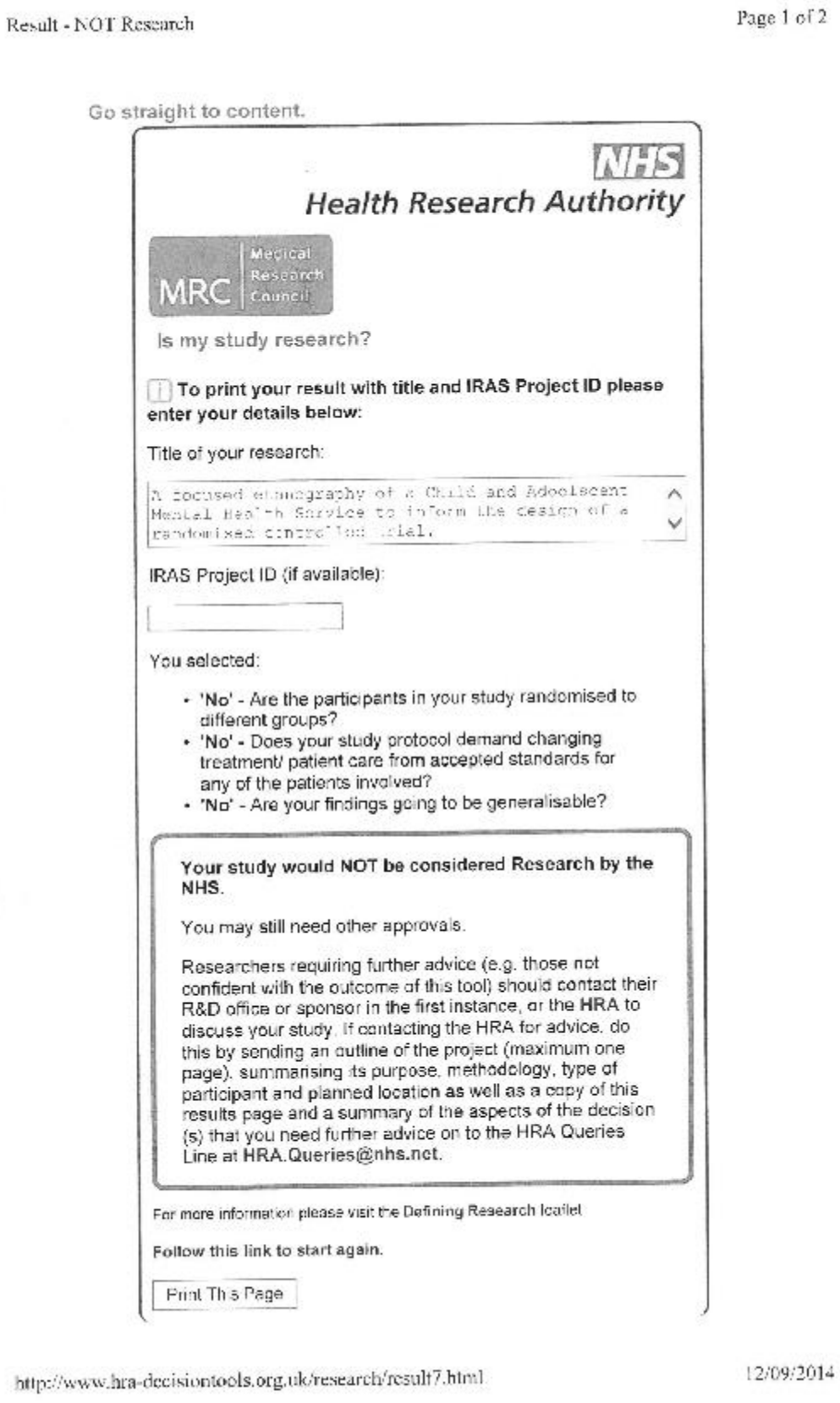
Please do not hesitate to contact me should you have any questions. Good luck, I hope that the study goes well.

With best wishes,

David Ekers

Page 1 of 1

Stage I: Health Research Authority Research Assessment- Not Research



Result - NOT Research

Page 1 of 2

Go straight to content.

NHS
Health Research Authority

MRC Medical Research Council

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

A focused ethnography of a Child and Adolescent Mental Health Service to inform the design of a randomised controlled trial.

IRAS Project ID (if available):

You selected:

- 'No' - Are the participants in your study randomised to different groups?
- 'No' - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- 'No' - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision (s) that you need further advice on to the HRA Queries Line at HRA.Queries@nhs.net.

For more information please visit the Defining Research leaflet

Follow this link to start again.

Print This Page

http://www.hra-decisiontools.org.uk/research/result7.html

12/09/2014

Stage I: Approval of a Minor Ethical Amendment from the School of Medicine, Pharmacy and Health Ethics Sub-Committee

Durham University
School of Medicine, Pharmacy and Health

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Dr David Ekers
Clinical Senior Lecturer
Chair, School of Medicine, Pharmacy and Health Ethics Sub-Committee

Charlotte Kitchen
School of Medicine, Pharmacy and Health
Durham University

15 January 2015

Dear Charlotte,

Re: Request to extend ethical approval of Ethics Application ESC2/2014/06
A focused ethnography of a Child and Adolescent Mental Health Service to inform the design of a randomised controlled trial.

As Chair of the Ethic's Sub-Committee I have reviewed and approved your request to extend ethical approval for your study 'A focused Ethnography of a Child and Adolescent Mental Health Service to inform the design of a randomised controlled trial' (ESC2/2014/06) to 10 March 2015, to enable appropriate data collection.

Good luck with your study and please contact me if you require any further information.

Kind regards,

David Ekers

Appendix 3

Stage I: Staff Information Sheet (Observation)

Information Sheet

A focused ethnography of a Child and Adolescent Mental Health Service to inform the design of a randomised controlled trial

Introduction

Hello, my name is Charlotte Kitchen and I work for the Mental Health Research Centre at Durham University. I am also working as a research assistant in the South Durham Child and Adolescent Mental Health Services (CAMHS) team. I am currently involved in the planning and design of a study to evaluate an intervention for depression in CAMHS. The purpose of my placement with the team is to learn and fully understand how the team operates and functions.

This is where I need your help! In order, to learn as much as I can, I would like to observe the everyday life of the team for three months and to take notes. At this stage I would like to ask your permission to make these observations.

Who is being asked to take part?

The whole team is being asked whether they would be happy for me to observe their normal day-to-day practice if and when I encounter them on my placement. This might range from regular contact with some members of staff to other members of staff who I never come into contact with.

What does taking part involve?

It involves you just conducting your everyday job roles and being your normal selves! Although I will be observing everyday practice, there will be no monitoring of individual performance. I will not be commenting on individual members of staff; the purpose of my project is to record practical barriers to a future depression intervention for young people. For example, I may comment upon normal intake procedures for the team. This should in no way be disruptive to your normal ways of working.

Do you have to take part?

No, participation is completely voluntary and you will not be asked to provide a reason if you do not want to take part. If you **do not** want to be involved please complete the "opt-out" form attached. However, if you do opt out due to the observational nature of the study I will still be on placement with the team and may be observing colleagues that you are interaction with but no comments will be recorded on your part in those interactions. If you do not complete the opt-out form it will be assumed that you are happy to take part.

Even if you do decide to take part, you can change your mind at any time during the research without giving a reason. If you do decide to stop taking part we will be able to use any information up to that point but we will not collect any further information. We are hoping that as many members of the team as possible will allow me to make notes on them to provide a more accurate picture of the current service.

What are the possible risks of taking part?

We are not anticipating any risks associated with involvement but in the unlikely situation that any risks are identified, the normal Trust procedures would be followed.

What are the benefits to taking part?

The notes taken will help to tailor the planned behavioural activation intervention trial for depression to be better suited to this unique setting meaning a better experience for both staff and patients.

What will happen to the observational data?

All data will be stored according to Trust and university procedures. All information will remain confidential (not shared with anyone outside the research team) and a de-identified version of the findings will be circulated to the team. No member of the team will be named in our findings. You will also be informed of the outcomes of these findings; in terms of what impact they have had on the design of the future trial, any publications or presentations.

Who to contact if you require further information or have a complaint?

If you have complaint or a concern please contact either myself or my supervisor;

Charlotte Kitchen
E113a Wolfson Building,
Durham University Queens Campus,
Thornaby,
Stockton-on-Tees
TS17 6BH
Telephone: 0191 33 40455
charlotte.kitchen@dur.ac.uk

Paul Tiffin
E107 Wolfson Building,
Durham University Queen's Campus,
Thornaby,
Stockton-on-Tees.
TS17 6BH
Telephone: 0191 33 40707
p.a.tiffin@dur.ac.uk

Stage I: Staff Opt-Out Form (Observation)

A focused ethnography of a Child and Adolescent Mental Health Service to inform a randomised controlled trial

*Please complete this form if you do **NOT** want to be commented upon in the researcher's observation study. Please return this form directly to the researcher or post it into the sealed box located in*

……..……(location of confidential box).

I (name)……..do **NOT** wish to participate in the study named above.

Signature……

Today's date……

Appendix 4

Stage I: Staff Information Sheet (Interview)

Information Sheet

A focused ethnography of a Child and Adolescent Mental Health Service to inform the design of a randomised controlled trial

Introduction

I have been conducting an observational project in the South Durham Child and Adolescent Mental Health Services (CAMHS) team over the past three months and I would like to follow up on some of my findings by interviewing key stakeholders from the service. You have been identified as one such key stakeholder.

What does taking part involve?

It involves an interview lasting a maximum of 40 minutes one-to-one with myself. You will be provided with a copy of the interview transcript to read and check that we have understood everything that was discussed. You will then have the opportunity to clarify any misunderstandings.

Do you have to take part?

No, participation is completely voluntary and you will not be asked to provide a reason if you do not want to take part. If you would like to take part you will need to finish reading the information sheet and complete the consent form provided. Even if you do decide to take part, you can change your mind at any time during the interview. If you do decide to stop taking part we will be able to use any information up until that point but we will not ask you for further information.

What are the possible risks of taking part?

Although we are not anticipating any risks associated with involvement, due to the small numbers of staff involved it may not be possible to completely ensure anonymity. However, we will make sure no members of staff are named in our findings.

What are the benefits to taking part?

This research will enable us to tailor the planned behavioural activation intervention trial for depression specifically to this service which is a unique opportunity. Your feedback will help clarify and put into context the findings from the earlier observational work. All the data collected will be fed into the design of the planned future intervention study to ensure it is better suited to the setting meaning a better experience for both staff and patients.

What will happen to your data?

The information will be digitally recorded on a Trust approved device and then transcribed word for word. The digital recording will then be securely destroyed. The data will be coded for common themes. All data will be stored according to Trust and university procedures. All information will remain confidential (not shared with anyone outside the research team) and a de-identified version of the findings will be circulated to the team. You will also be informed of the outcomes of these findings; in terms of what impact they have had on the design of the future trial, any publications or presentations.

Who to contact if you require further information or have a complaint?

If you have complaint or a concern please contact either myself or my supervisor;

Charlotte Kitchen
E113a Wolfson Building,
Durham University Queens Campus,
Campus,
Thornaby,
Stockton-on-Tees
TS17 6BH
Telephone: 0191 33 40455
charlotte.kitchen@dur.ac.uk

Paul Tiffin
E107 Wolfson Building,
Durham University Queen's
Thornaby,
Stockton-on-Tees.
TS17 6BH
Telephone: 0191 33 40707
p.a.tiffin@dur.ac.uk

Stage I: Staff Consent Form (Interview)

Participant Identification Number:

CONSENT FORM (INTERVIEWS)

Study Title: A focused ethnography of a Child and Adolescent Mental Health Service to inform the design of a randomised controlled trial.

Please initial the boxes to confirm you agree with each statement

1. I confirm that I have read and understand the information sheet dated 06/06/2014 (version 1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my legal rights being affected. I understand that any information collected up until the point of my withdrawal will be kept and used as part of the research. ☐

3. I understand that by taking part in this research I will be interviewed and I agree that the interview can be audio recorded. ☐

4. I agree to the use of my anonymised quotes when this research is published. ☐

5. I agree to take part in the above study.

Name of Participant:

Date

Signature

Name of Person taking consent (Researcher):

Date:

Signature:

Appendix 5

Behavioural Activation Session Agendas

Session 1: Getting Started

- Welcome
- Structure of BA therapy
- Rational for BA
- Introduction to the BA model- **individual formulation**
- Values, important people and activities
- Between-Session Tasks

Session 2: Getting Started II

- A guide for Parents/Carers
- Introduction to Mood Monitoring
- Introduction to Activity Charts

Session 3: Getting Active

- Mood vs. Goal Directed Behaviour
- Introduction to Avoidance (TRAP/TRAC)
- Goal-setting
- Introduction to Activity Scheduling

Session 4: Getting Active II

- Parenting skills
- Why we do what we do… payoff and cost**:** Situation-Action-Mood
- "Improve your Mood" vs. "Bring you Down Activities"

Session 5: Problem Solving

- Mini-Steps
- Monitoring Parental Support Behaviours
- Triggers
- Using COPE to manage challenging situations

Session 6: Goal-Setting

- Values Clarification
- Review Goal-setting
- Mini-steps to reach goals and values
- Active listening for parents/carers
- Identifying Barriers- internal/external

Session 7: Overcoming Barriers

- Overcoming Avoidance
- Avoidance Modification (TRAP/TRAC)
- Parental Strategies for Communicating Support

Session 8: Staying on Track

- Relapse Prevention
- Identification of Early Warning Signs
- Formulation of Relapse Prevention Plan
- Goodbye

Appendix 6

Stage II: Favourable Opinion Letter from the School of Medicine, Pharmacy and Health Ethics Sub-Committee

Durham University
School of Medicine, Pharmacy and Health

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Dr David Ekers
Clinical Senior Lecturer
Chair, School of Medicine, Pharmacy and Health Ethics Sub-Committee

Charlotte Kitchen
School of Medicine, Pharmacy and Health
Durham University

1st December 2014

Dear Charlotte,

Re: Ethics Application ESC2/2014/14
The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial

Thank you for sending the above application to the School of Medicine, Pharmacy and Health Ethics Committee for ethical review. The project was reviewed at a committee meeting on 22nd October 2014. The committee requested some changes to the application, and these have now been reviewed by myself as Chair. I am satisfied that all of the comments made by the committee at the meeting have been adequately addressed and I can therefore confirm Durham University ethical approval for the study.

Approval is given subject to the following:

- That you gain all relevant NHS REC, governance and Caldicott Guardian approvals prior to starting the research.
- That data generated for this study is maintained and destroyed as outlined in this proposal and in keeping with the Data Protection Act.
- If you make any amendments to your study, these must be approved by the School committee prior to implementation.
- At the end of the study, please submit a short end of study report (ESC3 form) to the School ethics committee.

Please do not hesitate to contact me should you have any questions.

Kind regards,

David Ekers

Page 1 of 1

Stage II: Approval of Minor Ethical Amendments from the School of Medicine, Pharmacy and Health Ethics Sub-Committee [7]

Durham University
School of Medicine, Pharmacy and Health

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Dr Angela Woods
Lecturer in Medical Humanities
Deputy Chair, School of Medicine, Pharmacy and Health Ethics Sub-Committee

Charlotte Kitchen
School of Medicine, Pharmacy and Health
Durham University

4 June 2015

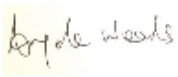
Dear Charlotte,

Re: Minor Amendment to Protocol for Ethics Application ESC2/2014/14
The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial

Thank you for sending in your minor amendment to protocol request for your study entitled 'The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial' (ESC2/2014/14). As Deputy Chair of the Ethic's Sub-Committee I have reviewed and approved your amendment.

Good luck with your study and please contact me if you require any further information.

Kind regards,



Angela Woods

Page 1 of 1

[7] Letters have been included where they were issued, other minor amendments were confirmed via email correspondence. No major amendments were submitted.

Durham University
School of Medicine, Pharmacy and Health

Shaped by the past, creating the future

Dr Shelina Visram
Lecturer in Medical Humanities
Deputy Chair, School of Medicine, Pharmacy and Health Ethics Sub-Committee

Charlotte Kitchen
School of Medicine, Pharmacy and Health
Durham University

4 January 2016

Dear Charlotte

Re: Minor Amendment to Protocol for Ethics Application ESC2/2014/14
The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial

Thank you for sending in your minor amendment request for your study entitled 'The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial' (ESC2/2014/14). As Deputy Chair of the Ethic's Sub-Committee I have reviewed and approved your amendments:

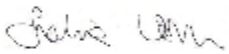
1. Study completion date to be extended from 04/07/2016 to 04/10/2016;

2. Two additional Research Assistants (Claire Farrow and Deborah Kemp) to be added to the study team.

Please can you let Susan Williams have an up-to-date CV for each of the additional Research Assistants for our file.

Good luck with your study and please contact me if you require any further information.

Kind regards



Shelina Visram

Durham University
School of Medicine, Pharmacy and Health

Shaped by the past, creating the future

Dr David Ekers
Clinical Senior Lecturer
Chair, School of Medicine, Pharmacy and Health Ethics Sub-Committee

Charlotte Kitchen
School of Medicine, Pharmacy and Health
Durham University

5th September 2016

Dear Charlotte

Re: Request to extend ethical approval of Ethics Application (ESC2/2014/14)

The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial

As Deputy Chair of the Ethic's Sub-Committee I have reviewed and approved your request to a minor amendment to extend ethical approval for your study (ESC2/2014/14) from 04/10/2016 to 31/12/2016 to ensure all the six month follow up assessments are completed and the appropriate data collected.

Kind regards

Shelina Visram
Deputy Chair

Stage II: Favourable Opinion Letter from NRES Committee North East-Newcastle and North Tyneside 1

NHS
Health Research Authority
NRES Committee North East - Newcastle & North Tyneside 1
Jarrow Business Centre
Jarrow REC Centre
Room 001
Rolling Mill Road
Jarrow
NE32 3DT

Telephone: 0191 428 3565

27 January 2015

Miss Charlotte E W Kitchen
PhD Student in the Mental Health Research Centre
Durham University
E113a Wolfson Building
Durham University Queens Campus
Stockton-on-Tees
TS17 6BH

Dear Miss Kitchen

Study title:	**The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial**
REC reference:	**15/NE/0002**
Protocol number:	**N/A**
IRAS project ID:	**156336**

Thank you for your letter of 26 January 2015, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Ms Gillian Mayer, nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a **Favourable** ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [I: Poster]	3	26 January 2015
Covering letter on headed paper [NRES Cover letter]		05 December 2014

Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [E; Durham University Personal Indemnity Insurance]		16 July 2014
GP/consultant information sheets or letters [W; GP Letter]	1	21 November 2014
Interview schedules or topic guides for participants [M; Qualitative Interview Topic Guide]	1	02 October 2014
Letter from sponsor [H; Sponsor Letter]		02 December 2014
Letters of invitation to participant [Q; Recruitment Letter]	1	02 October 2014
Letters of invitation to participant [R; Consent-to-Contact Form]	2	21 November 2014
Other [O; DE CV]		24 September 2014
Other [P; PW CV]		
Other [F; Durham University Public and Products Liability Insurance]		16 July 2014
Other [G; CAMHS Support Letter]		
Other [BA Fidelity Rating Sheet]		
Other [REC Response Letter]	1 (C Kitchen)	26 January 2015
Participant information sheet (PIS) [B; Initial Interview Workbook (Parents_Carers)]	3	26 January 2015
Participant information sheet (PIS) [C; Initial Interview Workbook (YP_16+)]	3	26 January 2015
Participant information sheet (PIS) [D; Initial Interview Workbook (YP_Under 16)]	3	26 January 2015
Participant information sheet (PIS) [V; Interview Info &; Consent (Clinician)]	2	26 January 2015
REC Application Form [REC_Form_22122014]		22 December 2014
Referee's report or other scientific critique report [T; Review Letter]		10 October 2014
Research protocol or project proposal [Study Protocol]	7	21 November 2014
Summary CV for Chief Investigator (CI) [S; CK CV]		
Summary CV for supervisor (student research) [N; PT CV]		06 October 2014
Validated questionnaire [U; K-SADS-PL]	1.0	01 October 2006
Validated questionnaire [J; 3 Month Interview Workbook (Parents_Carers)]	1	30 September 2014
Validated questionnaire [K; 3 Month Interview Workbook (YP_16+)]	1	02 October 2014
Validated questionnaire [L; 3 Month Interview Workbook (YP_u16)]	1	02 October 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

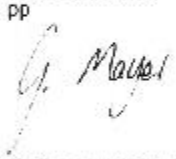
HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

15/NE/0002	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely
pp



Professor Philip Preshaw
Chair

Email: nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net

Enclosures: 'After ethical review – guidance for researchers'

Copy to: *Dr Paul Tiffin – Academic Supervisor, G005 Wolfson Building, Durham University*

Ms Jackie Mitchell - Tees, Esk and Wear Valleys NHS Foundation Trust

Stage II: Approval of Minor Ethical Amendments from NRES Committee North East- Newcastle and North Tyneside 1

NHS
Health Research Authority
NRES Committee North East - Newcastle & North Tyneside 1
Jarrow Business Centre
Room 001
Viking Industrial Park
Rolling Mill Road
Jarrow
NE32 3DT

Tel: 0191 428 3384

10 April 2015

Miss Charlotte E W Kitchen
PhD Student in the Mental Health Research Centre
Durham University
E113a Wolfson Building
Durham University Queens Campus
Stockton-on-Tees
TS17 6BH

Dear Miss Kitchen

Study title:	**The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial**
REC reference:	**15/NE/0002**
Protocol number:	**N/A**
Amendment number:	**Minor Amendment - additional supervisor, 20/02/15**
Amendment date:	**20 February 2015**
IRAS project ID:	**156336**

Thank you for your letter of 20 February 2015, notifying the Committee of the above amendment.

This amendment has been submitted in order to include an additional supervisor to the project (Dr Sue Lewis), and also make a change to the second Child and Adolescent Mental Health Services recruitment site from 'Teesside' to 'North Durham'. This team is still within the same Trust.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
Notice of Minor Amendment	Minor Amendment - additional supervisor, 20/02/15	20 February 2015
Summary CV for supervisor (student research)	S. Lewis	

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

15/NE/0002: Please quote this number on all correspondence

Yours sincerely

Sarah Prothero

Sarah Prothero
REC Assistant

E-mail: nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net

Copy to: *Ms Jackie Mitchell, Tees, Esk and Wear Valleys NHS Foundation Trust*
Dr Paul Tiffin, Durham University

NHS
Health Research Authority
NRES Committee North East - Newcastle & North Tyneside 1
Jarrow Business Centre
Room 001
Viking Industrial Park
Rolling Mill Road
Jarrow
NE32 3DT

Tel: 0191 428 3384

18 June 2015

Miss Charlotte E W Kitchen
PhD Student in the Mental Health Research Centre
Durham University
E113a Wolfson Building
Durham University Queens Campus
Stockton-on-Tees
TS17 6BH

Dear Miss Kitchen

Study title:	**The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial**
REC reference:	**15/NE/0002**
Protocol number:	**N/A**
Amendment number:	**Minor Amendment - updated protocol, 26/05/15**
Amendment date:	**04 June 2015**
IRAS project ID:	**156336**

Thank you for your letter of 04 June 2015, notifying the Committee of the above amendment.

This amendment has been submitted to include an updated protocol, removing reference to the manual being used as the same as at Reading University. This information is now incorrect as two different manuals are being used.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Notice of Minor Amendment	Minor Amendment - updated protocol, 26/05/15	04 June 2015
Research protocol or project proposal	7	21 November 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

15/NE/0002:	**Please quote this number on all correspondence**

Yours sincerely

Sarah Prothero

Sarah Prothero
REC Assistant

Email: nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net

Copy to: *Ms Jackie Mitchell, NHS, research and development team*
Dr Paul Tiffin, Durham University Queens Campus

NHS
Health Research Authority

NRES Committee North East - Newcastle & North Tyneside 1
Jarrow Business Centre
Room 001
Viking Industrial Park
Rolling Mill Road
Jarrow
NE32 3DT

10 September 2015

Miss Charlotte E W Kitchen
PhD Student in the Mental Health Research Centre
Durham University
E113a Wolfson Building
Durham University Queens Campus
Stockton-on-Tees
TS17 6BH

Dear Miss Kitchen

Study title:	**The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial**
REC reference:	**15/NE/0002**
Protocol number:	**N/A**
Amendment number:	**Amendment 2**
Amendment date:	**10.09.2015**
IRAS project ID:	**156336**

Thank you for your letter, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Other [NRES_Minor_Ammendment_Letter (2)]		06 August 2015

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

15/NE/0002:	Please quote this number on all correspondence

Yours sincerely

Ben Morrison
REC Administration Assistant

Email: nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net

Copy to: *Ms Jackie Mitchell, NHS, research and development team*
Dr Paul Tiffin

NHS
Health Research Authority
North East - Newcastle & North Tyneside 1 Research Ethics Committee
Jarrow Business Centre
Room 001
Viking Industrial Park
Rolling Mill Road
Jarrow
NE32 3DT

Tel: 0191 428 3476

12 February 2016

Miss Charlotte E W Kitchen
PhD Student in the Mental Health Research Centre
Durham University
E113a Wolfson Building
Durham University Queens Campus
Stockton-on-Tees
TS17 6BH

Dear Miss Kitchen

Study title:	**The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial**
REC reference:	**15/NE/0002**
Amendment number:	**Minor Amendment 4**
Amendment date:	**23 December 2015**
IRAS project ID:	**156336**

Thank you for your letter of 23 December 2015, notifying the Committee of the above amendment.

The amendment has been considered by the [Chair and the Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Notice of Minor Amendment	Minor Amendment 4	23 December 2015

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

15/NE/0002:	**Please quote this number on all correspondence**

Yours sincerely

Donna Bennett
REC Assistant

Email: nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net

Copy to: *Ms Jackie Mitchell, NHS, research and development team*

Dr Paul Tiffin, Durham University Queens Campus

KITCHEN, CHARLOTTE E.W.

From: NewcastleandNorthTyneside1 NRESCommittee.NorthEast- (HEALTH RESEARCH AUTHORITY) <nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net>
Sent: 10 October 2016 15:01
To: KITCHEN, CHARLOTTE E.W.
Subject: 15/NE/0002 IRAS Project ID 156336 Acknowledgement and confirmation of Amendment Categorisation 10.10.2016

Dear Charlotte,

IRAS Project ID:	156336
REC Reference:	15/NE/0002
Short Study Title:	Behavioural Activation Therapy for Young People with Depression: V1
Date complete amendment submission received:	31st August 2016
Amendment No./ Sponsor Ref:	Non-Substantial Amendment 1
Amendment Date:	31st August 2016
Amendment Type:	**Non-substantial**

Thank you for notifying the HRA (which manages the Research Ethics Service in England) of the above amendment.

Non-substantial amendments do not require an ethical opinion from the Research Ethics Committee and do not need to be notified to the Committee. Please follow the guidance in the Categorisation section below to ensure that the amendment is notified appropriately to NHS/HSC R&D offices. You should also take note of the Confirmation of Assessment Arrangements section for information on when you may implement this amendment at participating NHS organisations in England.

Categorisation of Amendment

In line with the UK Process for Handling UK Study Amendments I can confirm that this amendment has been categorised as:

Category C - An amendment that has no implications that require management or oversight by the participating NHS organisations

As such, the sponsor may implement this amendment **as soon as any relevant regulatory approvals are in place** (for participating organisations in England, please see 'Confirmation of Assessment Arrangements' below).

As Chief Investigator/Sponsor, it remains your responsibility to ensure that the research management offices and local research teams (if applicable) at each of your participating organisations are informed of this amendment.

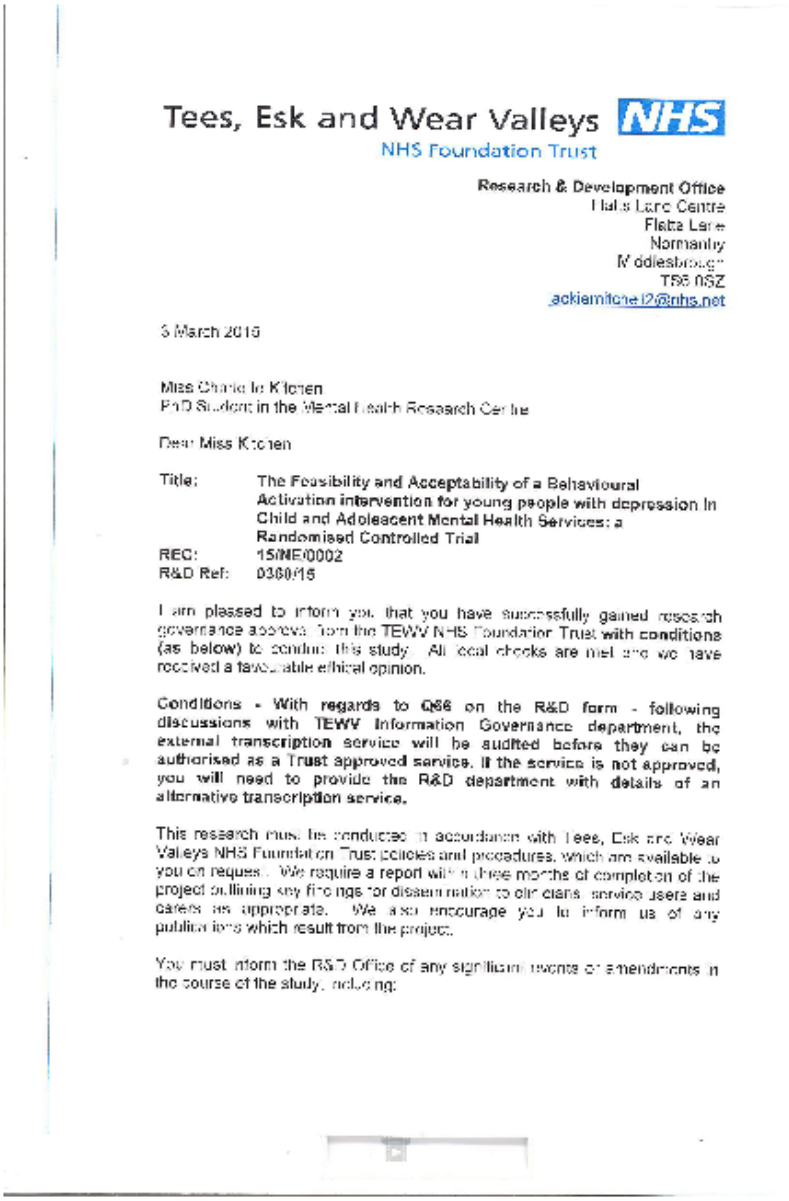
Note: you may only implement changes described in the amendment notice or letter.

Participating NHS Organisations in England – Confirmation of Assessment Arrangements

Further to the details above, I can confirm that no HRA assessment of this amendment is needed.

- If this study has HRA Approval, this amendment may be implemented at participating NHS organisations in England once the conditions detailed in the categorisation section above have been met

Stage II: Research and Development Approval Letters [8]



Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

Research & Development Office
Flatts Lane Centre
Flatts Lane
Normanby
Middlesbrough
TS6 0SZ
jackiemichie12@nhs.net

3 March 2015

Miss Charlotte Kitchen
PhD Student in the Mental Health Research Centre

Dear Miss Kitchen

Title: The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial
REC: 15/NE/0002
R&D Ref: 0360/15

I am pleased to inform you that you have successfully gained research governance approval from the TEWV NHS Foundation Trust with conditions (as below) to conduct this study. All local checks are met and we have received a favourable ethical opinion.

Conditions - With regards to Q66 on the R&D form - following discussions with TEWV Information Governance department, the external transcription service will be audited before they can be authorised as a Trust approved service. If the service is not approved, you will need to provide the R&D department with details of an alternative transcription service.

This research must be conducted in accordance with Tees, Esk and Wear Valleys NHS Foundation Trust policies and procedures, which are available to you on request. We require a report within three months of completion of the project outlining key findings for dissemination to clinicians, service users and carers as appropriate. We also encourage you to inform us of any publications which result from the project.

You must inform the R&D Office of any significant events or amendments in the course of the study, including:

[8] Letters have been included where they were issued, other minor amendments were confirmed via email correspondence.

- Early termination of the study, or continuation beyond the stated end date
- Significant adverse events
- Significant amendments to the study protocol

The Trust R&D Office conducts a yearly audit of research governance compliance, and you will be informed in advance if this study is due to be audited.

I would like to take this opportunity to wish you every success with your research. If there is any way that we can assist you in the future please contact us.

Yours sincerely

Jackie Mitchell
R&D Manager (Acting)

Cc: Paul Tiffin

Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

RESEARCH AND DEVELOPMENT OFFICE
Flatts lane Centre
Flatts Lane
Normanby
Middlebrough
TS6 0SZ

22 February 2016

Miss Charlotte Kitchen
PhD Student in the Mental Health Research Centre

Dear Miss Kitchen

Title: **The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial**
REC: **15/NE/0002**
R&D Ref: **0360/15**

Thank you for submitting details of **minor amendment 4 dated** 23 December 2015 to the above study which includes:

Document	Version	Date
Notice of Minor Amendment (non-CTIMP)	Minor Amendment 4	23 December 2015

Following review of the above amendment we can confirm that Tees, Esk & Wear Valleys NHS Foundation Trust can accommodate changes proposed.

The amendment may therefore be immediately implemented at this site under the existing NHS Permission. Please note that you may only implement changes that were described in the amendment notice or letter.

Yours sincerely

Sarah Daniel
R&D Manager

Stage II: University Sponsor Letter and Insurance Cover

Durham University
School of Medicine, Pharmacy and Health

2nd December 2014

To Whom it May Concern

Re: The Feasibility and Acceptability of a Behavioural Activation intervention for young people with depression in Child and Adolescent Mental Health Services: a Randomised Controlled Trial

I am writing in my capacity as Head of the School of Medicine, Pharmacy and Health at Durham University to inform you of our departmental support and sponsorship of the above study which is being conducted by Charlotte Kitchen who is a postgraduate research student studying for a PhD within our School.

I ask you to note that the University is sponsoring and indemnifying this research project. I can also confirm that the project has been reviewed by our Ethics Committee and that ethical approval for the study has been granted.

I would like to commend the study to you for its potential to make an important contribution to our understanding of means by which we can improve the health and well-being of young people who experience depression.

Yours sincerely,

Dr Simon Forrest

Head of School, School of Medicine, Pharmacy and Health
Durham University

Hasilwood House
60 Bishopsgate
London EC2N 4AW
Tel: 020 7847 8670
Fax: 020 7847 8689

TO WHOM IT MAY CONCERN

16th July 2014

Dear Sir/Madam

THE UNIVERSITY OF DURHAM
AND ALL ITS SUBSIDIARY COMPANIES

We confirm that the above Institution is a Member of U.M. Association Limited, and that the following covers are currently in place:-

PUBLIC AND PRODUCTS LIABILITY

Certificate of Entry No.	UM050/00
Period of Cover	1 August 2014 to 31 July 2015
Includes	Indemnity to Principals
Limit Of Indemnity	£25,000,000 any one event and in the aggregate in respect of Products Liability and unlimited in the aggregate in respect of Public Liability.
Cover provided by	U.M. Association Limited and Excess Insurers

If you have any queries in respect of the above details, please do not hesitate to contact us.

Yours faithfully

Susan Wilkinson
For U.M. Association Limited

Hasilwood House
60 Bishopsgate
London EC2N 4AW
Tel: 020 7847 8670
Fax: 020 7847 8689

TO WHOM IT MAY CONCERN

16th July 2014

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Limit of Indemnity	£10,000,000 any one claim and in the aggregate except for Pollution where cover is limited to £1,000,000 in the aggregate.
Cover provided by	U.M. Association Limited and Excess Cover Providers led by CNA Insurance Company Limited

If you have any queries in respect of the above details, please do not hesitate to contact us.

Yours faithfully

Susan Wilkinson
For U.M. Association Limited

Hasilwood House
60 Bishopsgate
London EC2N 4AW
Tel: 020 7847 8670
Fax: 020 7847 8689

TO WHOM IT MAY CONCERN

20th July 2015

Dear Sir/Madam

THE UNIVERSITY OF DURHAM
AND ALL ITS SUBSIDIARY COMPANIES

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Yours faithfully

Susan Wilkinson
For U.M. Association Limited

Hasilwood House
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TO WHOM IT MAY CONCERN

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If you have any queries in respect of the above details, please do not hesitate to contact us.

Yours faithfully

Susan Wilkinson
For U.M. Association Limited

ISO 9001

U.M. Association Limited
Registered Office: Hasilwood House, 60 Bishopsgate, London, EC2N 4AW
Registered in England and Wales No. 2731799

Hasilwood House
60 Bishopsgate
London EC2N 4AW
Tel: 020 7847 8670
Fax: 020 7847 8689

TO WHOM IT MAY CONCERN

18th July 2016

Dear Sir/Madam

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TO WHOM IT MAY CONCERN

18th July 2016

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If you have any queries in respect of the above details, please do not hesitate to contact us.

Yours faithfully

Susan Wilkinson
For U.M. Association Limited

Appendix 7

Stage II: Invitation Letter

The BUDDY Study

[*Date*]

Dear [*insert parent/carer's name*],

The [*insert team name*] Child and Adolescent Mental Health Services (CAMHS) team are working with researchers at Durham University to look at how we treat low mood. We want to ask young people to provide feedback on the treatments we normally provide and a new option for treatment so we can find out what works best.

[You/your young person is/are] being invited to take part in the study because during your first assessment [you/your young person] reported symptoms of low mood meaning [you/they] may be suitable to take part. Taking part in the study involves two assessments and a telephone call (and possibly an interview).

We have enclosed an information sheet about the study but we know that you will need more information in order to decide whether [you/[and] your young person] would like to take part. We would like to invite you to meet with Charlotte so that she can explain the study further.

Please indicate whether or not you would be happy to receive more information by completing the enclosed 'Contact form' and return it using the pre-paid envelope (just post directly into a post box- no stamp required). You will receive an appointment letter once we receive your contact form. [You/your young person] will receive £10 in vouchers just for attending this information meeting.

In the meantime, if you have any questions or would like let the research team know by telephone please call Charlotte Kitchen, on 0191 33 40455 or email: charlotte.kitchen@durham.ac.uk

Many thanks for taking the time to read this letter.

Kind Regards,

[*Insert team*] Child and Adolescent Mental Health Services team

Durham University

Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

The BUDDY Study

Permission for Researcher to Contact You

Name (of young person):

……

I am happy to be contacted.

If you tick this box the research team will send you an appointment letter to meet with Charlotte so you can receive more information. This does not mean you have to take part in the study- you are only agreeing to receive more information.

☐

I do not want to be contacted.

If you tick this box the research team will not contact you again.

☐

Insert ID number

Stage II: Parent/Carer Baseline Workbook (including Information Sheet, Consent Form and Self-Report Baseline Outcome Measures)

Durham University

Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

The BUDDY Study

A guide for Parents and Carers of young people under 16

DURHAM UNIVERSITY IN PARTNERSHIP WITH TEES, ESK & WEAR VALLEYS NHS FOUNDATIN TRUST

Charlotte Kitchen
Wolfson Building
Durham University Queens Campus
University Boulevard
Stockton-on-Tees, TS17 6BH

Phone: 0191 33 40455
E-mail: charlotte.kitchen@dur.ac.uk

Working together to improve forever

Participant ID number:

Information Sheet

Who am I?

My name is Charlotte Kitchen, I am a student at Durham University and I also work in Child and Adolescent Mental Health Services.

I would like to ask you and your young person to take part in a study to find out which treatments are best suited for young people with low mood. This will help us to offer treatments that young people and their caregivers like and find helpful.

What will happen in the study?

Your young person will have a more in-depth assessment than they would normally have. You will be asked to complete a questionnaire about your young person and to provide details about their health.

We can then see if they are suitable for the treatment we are offering. Some young people may not be suitable.

If they are suitable they will be given either:

1) **Combined Treatment: this will be tailored to your young person and may include interpersonal, family or cognitive behavioural therapy. This is the type of care they would receive if they were not involved in the study.**

2) **Behavioural Activation Therapy: this will be tailored to your young person for eight one hour sessions. This is a talking therapy based on the idea that if you become more active, in terms of family, physical and social activities, your mood will improve. This type of treatment is not normally available.**

We are asking your permission to consider either treatment option when planning your young person's care.

Everyone who takes part will have an extra assessment and telephone call to check on their progress after treatment. Some families will be offered an interview to provide in-depth feedback.

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Participant ID number:

What are the benefits of taking part?

- **Your young person may receive therapy that is not normally available in your area.**
- **Your young person will receive at least one extra assessment which will help staff to better plan their care.**
- **Your feedback could improve the care and services young people in your area receive.**
- **Your young person will receive £10 in vouchers each time they meet with a researcher as a thank you for their time (up to a maximum of £30).**

Are there any negatives to taking part?

Your young person will not get to choose which treatment they receive; it will be chosen by chance. Half of those who take part will receive treatment one and the other half will receive treatment two.

What will we do with the information collected?

A lot of the information we will be using is normally collected by the service so this will be stored as normal. Any extra information will be stored confidentially (not shared with anyone outside of the care and research team) inline with NHS and university policies.

When we have finished the study we will inform others about what we have found; it will be impossible for others to realise which young people have taken part and they will never be named.

You do not have to agree to your young person taking part (even if they would like to) and there will be no penalties for not participating.

If you have any questions please contact Charlotte Kitchen:

0191 33 40455
charlotte.kitchen@dur.ac.uk

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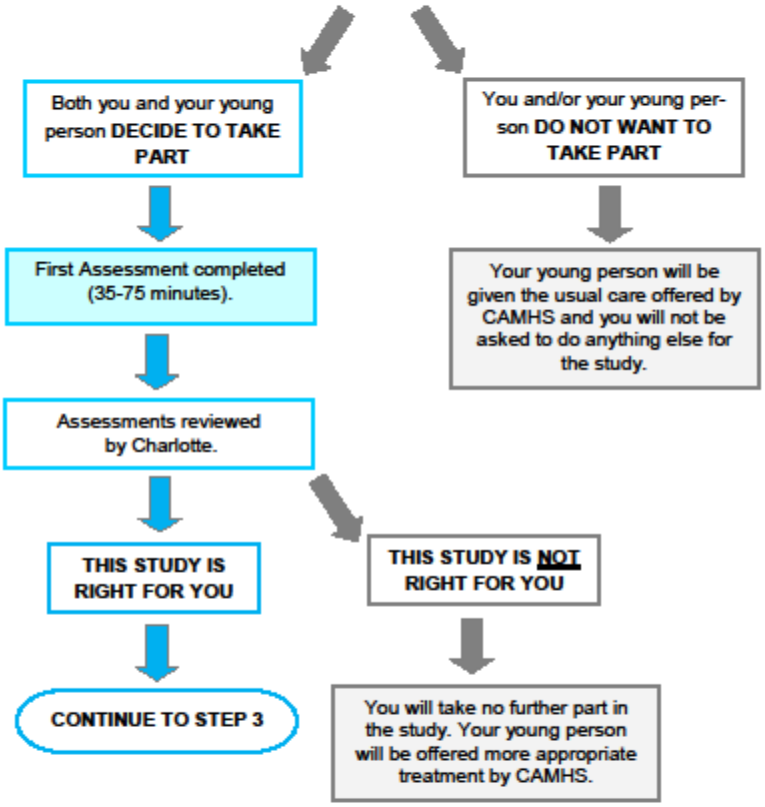
Participant ID number:

What will we ask you to do?

STEP 1 **Meet Charlotte at Child and Adolescent Mental Health Services (CAMHS). The research will be explained.**

STEP 2 **You and your young person will be asked to take part.**



STEP 3 **Some young people will have the Combined Treatment and others will have Behavioural Activation. A computer will put half the young people into each treatment group so that everyone has an equal chance to be in each group.**

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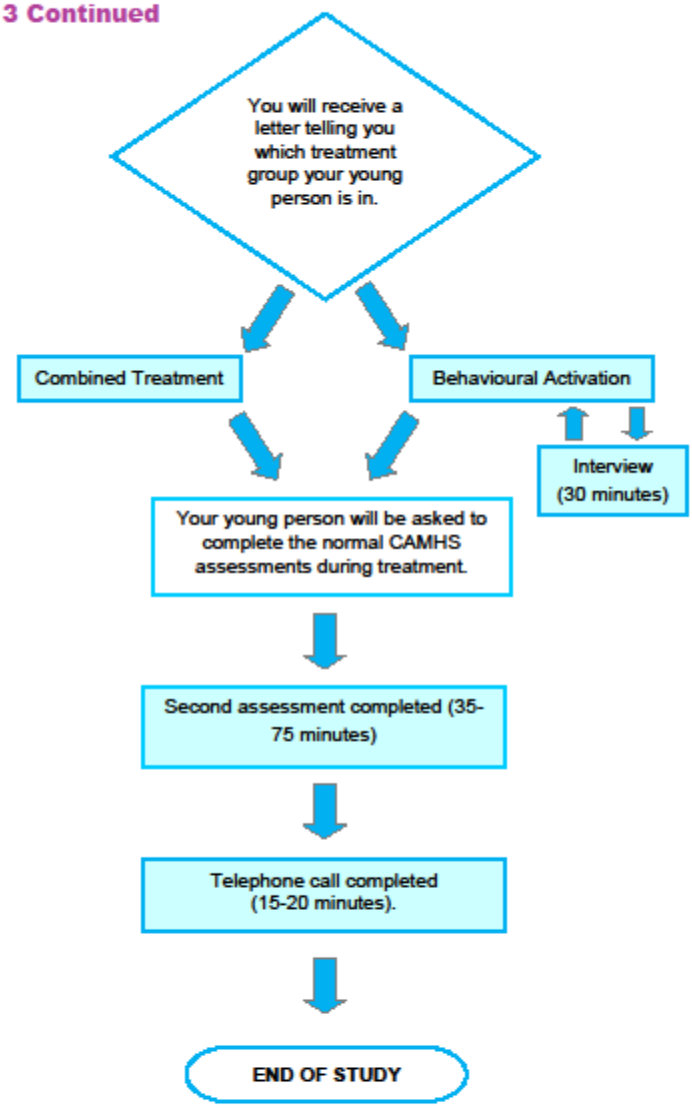
Participant ID number:

STEP 3 Continued



If at **any** time you decide you do <u>not</u> want your young person to continue taking part, you can leave the study and they will not be asked to provide any further information (we will use anything they have provided up until that point).

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Participant ID number:

Consent Form

PROJECT TITLE: The BUDDY Study

	Please tick each box to confirm that you agree with each statement
I have read and understood the information sheet. I have had the opportunity to consider the information and ask questions.	☐
I understand that both my own and my young person's participation is voluntary and that we are free to withdraw at any time without giving a reason and without any consequences. I understand that if we do withdraw, any information collected up until that point will be kept and used as part of the research.	☐
I understand that relevant sections of my young person's medical notes will be viewed by the research team.	☐
I am happy for the research team to contact my young person's GP.	☐
I understand that the treatment sessions may be audio recorded.	☐
I agree to the use of anonymised quotes when this research is published.	☐
I agree for my young person to take part in the above study.	☐

Name of young person: ……

Name of parent/carer: ……

Date: ……

Signature: ……

Name of person taking consent: ……

Date: ……

Signature: ……

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Participant ID number:

Mood and Feelings Questionnaire– Parent Version

This form is about how your child might have been feeling or acting recently. Please tick the box next to the statement that best describes your child over the PAST TWO WEEKS

	Not true	Sometimes	True
1. S/he felt miserable or unhappy			
2. S/he didn't enjoy anything at all			
3. S/he was less hungry than usual			
4. S/he ate more than usual			
5. S/he felt so tired s/he just sat around and did			
6. S/he was moving and walking more slowly than			
7. S/he was very restless			
8. S/he felt s/he was no good anymore			
9. S/he blamed her/himself for things that weren't			
10. It was hard for her/him to make up her/his mind			
11. S/he felt grumpy and cross with you			
12. S/he felt like talking less than usual			
13. S/he was talking more slowly than usual			
14. S/he cried a lot			
15. S/he thought there was nothing good for her/him			
16. S/he thought that life wasn't worth living			
17. S/he thought about death or dying			
18. S/he thought her/his family would be better off			
19. S/he thought about killing her/himself			
20. S/he didn't want to see her/his friends			
21. S/he found it hard to think properly or concen-			
22. S/he thought bad things would happen to her/			

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Participant ID number:

Mood and Feelings Questionnaire– Parent Version Continued

Please tick the box next to the statement that best describes your child in the PAST TWO WEEKS

	Not true	Sometimes	True
23. S/he hated him/herself			
24. S/he felt s/he was a bad person			
25. S/he thought s/he looked ugly			
26. S/he worried about aches and pains			
27. S/he felt lonely			
28. S/he thought nobody really loved her/him			
29. S/he didn't have any fun at school			
30. S/he thought s/he could never be as good as other kids			
31. S/he felt s/he did everything wrong			
32. S/he didn't sleep as well as s/he usually sleeps			
33. S/he slept a lot more than usual			
34. S/he wasn't as happy as usual, even when you praised or rewarded her/him			

Assessment Date	

MFQ Parent Report on Child
(http://devepi.duhs.duke.edu/instruments/MFQ%20%20Parent%20Report%20on%20Child%20-

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Participant ID number:

Thank you for taking the time to complete this workbook.

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Participant ID number:

Stage II: Young Person (aged 16-17) Baseline Workbook (including Information Sheet, Consent Form and Self-Report Baseline Outcome Measures)

Durham University

Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

The BUDDY Study

A Guide for Young People aged 16 and over

DURHAM UNIVERSITY IN PARTNERSHIP WITH TEES, ESK & WEAR VALLEYS NHS FOUNDATION TRUST

Charlotte Kitchen
Wolfson Building
Durham University Queens Campus
University Boulevard
Stockton-on-Tees, TS17 6BH

Phone: 0191 33 40455
E-mail: charlotte.kitchen@dur.ac.uk

Working together to improve forever

Participant ID number:

Information about the study

Who am I?

My name is Charlotte Kitchen, I am a student at Durham University and I also work in Child and Adolescent Mental Health Services.

I would really like to know how you feel about your care.

I want to find out which treatments work best for young people with low mood.

This will help us to offer treatments that young people like and find helpful.

What will happen in the study?

You will have a more detailed assessment than normal with Charlotte. We will ask you to complete some short questionnaires and to provide information about yourself.

We can then see if you are suitable for the treatments we are offering. Some young people may not be suitable.

If we ask you to join the study, you will be given either:

1) **Combined Treatment: this will be tailored to you and may include interpersonal, family or cognitive behavioural therapy. This is the type of treatment that you would receive if you were not taking part in the study.**

2) **Behavioural Activation therapy: this will be tailored to you over eight one hour sessions. Behavioural Activation is a talking therapy that helps improve the way you feel by increasing the time you spend with your family, friends and doing activities. This type of treatment is not normally available.**

We are asking you if it is alright to consider either treatment option when we plan your care.

Everyone who takes part will have an extra assessment and telephone call to check on their progress after treatment. Some people will be Asked to provide more in-depth feedback in an interview.

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Participant ID number:

Further Information

What are the benefits of taking part?

- You may receive therapy that is not normally available in your area.
- You will have at least one extra assessment which will help staff to better plan your care.
- Your feedback will help us to understand what works well and what could be improved so that we can provide better care.
- You will receive £10 in vouchers each time you meet with a researcher as a thank you for your time (up to a maximum of £30).

Are there any negatives to taking part?

You will not choose which treatment you receive, it will be decided by chance (like the toss of a coin) : half of those who take part will receive treatment one and the rest will receive treatment two.

What will we do with the information we collect?

Most of the information we will use is normally collected by your care team so will be stored as usual. Any extra data will not shared with anyone outside of your care and research team.

When we have finished the study we will want to tell others about what we have found but no one will be able to tell that it was you that has taken part; we will never use your name.

You can say yes or no. It is up to you whether you take part.

If you have any questions please contact Charlotte Kitchen:

0191 33 40455
charlotte.kitchen@dur.ac.uk

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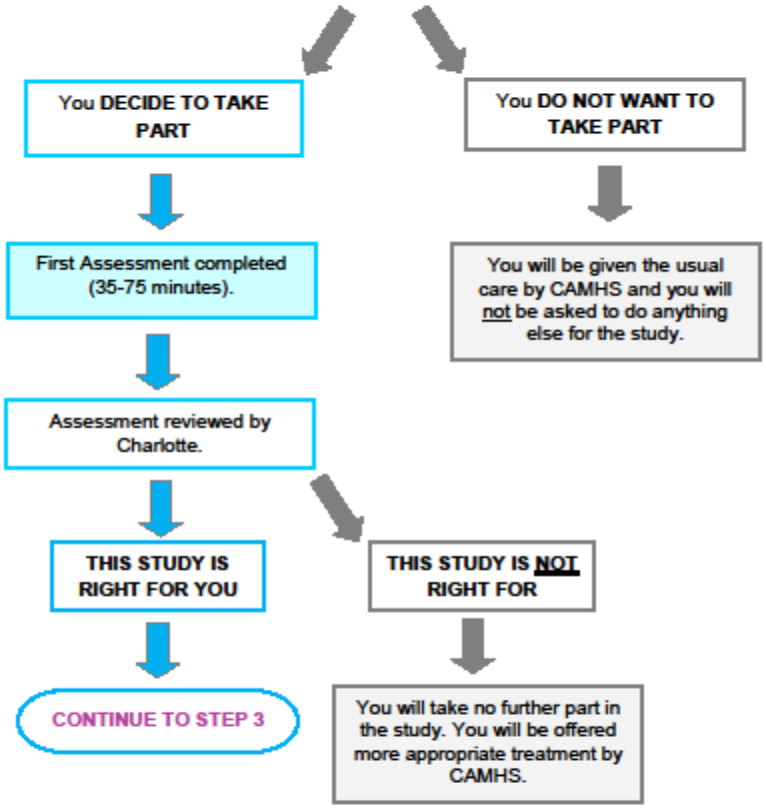
Participant ID number:

What exactly will happen?

STEP 1 **Meet Charlotte at Child and Adolescent Mental Health Services (CAMHS). Charlotte will explain the study.**

STEP 2 **Charlotte will ask if you would like to take part.**



STEP 3 **Some young people will have the Combined Treatment and others will have Behavioural Activation. A researcher will put half the young people into each treatment group using a computer so that everyone has an equal chance to be in each group.**

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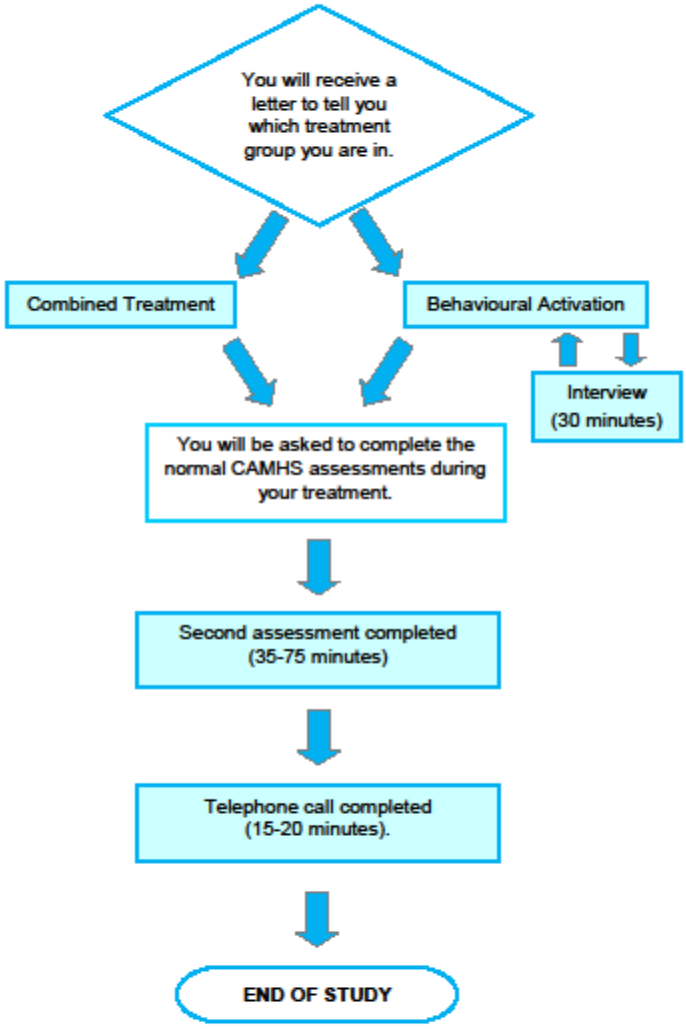
Participant ID number:

STEP 3 Continued



If at **any** time you decide you do **not** want to take part, you can leave the study and you will not be asked to provide any further information (we will use anything you have provided up until that point).

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Participant ID number:

Consent Form

If you would like to take part in 'The BUDDY Study' please read the following statements:

1. I have read and understood the information for the above study. I have had the opportunity to think about the information and ask questions.

2. I understand that I can stop taking part at any time during the study without giving a reason. I know that whatever I decide will not affect my medical care.

3. I understand that the researchers will need to see my medical notes.

4. I am happy for the researchers to contact my GP.

5. I understand that my treatment sessions will be recorded.

6. I know that the team might use some of my responses when they report the study but they will never tell anyone my name.

If you understand the statements above, you now need to decide whether you would like to take part in the study.

I agree to take part in the above study. **Tick yes or no.**

☐ **YES** ☐ **NO**

Your Name: ……

Date: ……

Signature: ……

Name of Person taking Consent: ……

Date: ……

Signature: ……

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Participant ID number:

Mood and Feelings Questionnaire– Child Version

This form is about how you have been feeling or acting recently. Please tick the box next to the statement that best describes how you have been feeling or acting over the PAST TWO WEEKS

	Not true	Sometimes	True
1. I felt miserable or unhappy			
2. I didn't enjoy anything at all			
3. I was less hungry than usual			
4. I ate more than usual			
5. I felt so tired I just sat around and did nothing			
6. I was moving and walking more slowly than usual			
7. I was very restless			
8. I felt I was no good anymore			
9. I blamed myself for things that weren't my fault			
10. It was hard for me to make up my mind			
11. I felt grumpy and cross with my parents			
12. I felt like talking less than usual			
13. I was talking more slowly than usual			
14. I cried a lot			
15. I thought there was nothing good for me in the			
16. I thought that life wasn't worth living			
17. I thought about death or dying			
18. I thought my family would be better off without			
19. I thought about killing myself			
20. I didn't want to see my friends			
21. I found it hard to think properly or concentrate			
22. I thought bad things would happen to me			

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Participant ID number:

Mood and Feelings Questionnaire– Child Version Continued

Please tick the box next to the statement that best describes how you have been feeling or acting over the PAST TWO WEEKS

	Not true	Sometimes	True
23. I hated myself			
24. I felt I was a bad person			
25. I thought I looked ugly			
26. I worried about aches and pains			
27. I felt lonely			
28. I thought nobody really loved me			
29. I didn't have any fun in school			
30. I thought I could never be as good as other kids			
31. I did everything wrong			
32. I didn't sleep as well as I usually sleep			
33. I slept a lot more than usual			

Assessment Date	

MFQ Child Self Report
(http://devepi.duhs.duke.edu/instruments/MFQ%20%20Parent%20Report%20on%20Child%20-

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Participant ID number:

Rosenberg's Self-Esteem Scale

Below is a list of statements dealing with your general feelings about yourself. Please tick the box that best describes how you feel about the statement.

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. I feel that I am a person of worth, at				
2. I feel that I have a number of good				
3. All in all, I am inclined to feel that I am a				
4. I am able to do things as well as most				
5. I feel I do not have much to be proud of				
6. I take a positive attitude toward myself				
7. On the whole, I am satisfied with myself				
8. I wish I could have more respect for myself				
9. I certainly feel useless at times				
10. At times I think I am no good at all				

Assessment Date	

Rosenberg's Self-Esteem Scale (http://www.wwnorton.com/college/psych/psychsci/media/rosenberg.htm)

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Participant ID number:

Behavioral Activation for Depression Scale

Please read each statement carefully and then tick the box which best describes how much the statement was true for you DURING THE PAST WEEK, INCLUDING TODAY.

0= Not at all 1 2= A little 3 4= A lot 5 6= Completely	1	2	3	4	5	6
1. There were certain things that I needed to do that I didn't do.						
2. I am content with the amount and types of things that I did.						
3. I engaged in many different activities.						
4. I made good decisions about what type of activities and/or						
5. I was an active person and accomplished the goals I set out						
6. Most of what I did was to escape from or avoid something						
7. I spent a long time thinking						
8. I engaged in activities that would distract me from feeling						
9. I did things that were						
10. At times I think I am no good						

Assessment Date	

Kanter, J. W., Mulick, P. S., Busch, A. M., Berlin, K. S., & Martell, C. R. . (2012) . Behavioral Activation for Depression Scale (BADS) (Short Form). Measurement Instrument Database for the Social Science.

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Participant ID number:

Thank you for taking the time to complete this workbook.

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Participant ID number:

Stage II: Young Person (aged 12-15) Baseline Workbook (including Information Sheet, Consent Form and Self-Report Baseline Outcome Measures)

Durham University

Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

The BUDDY Study

A Guide for Young People under 16

DURHAM UNIVERSITY IN PARTNERSHIP WITH
TEES, ESK & WEAR VALLEYS NHS FOUNDATION TRUST

Charlotte Kitchen
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University Boulevard
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Phone: 0191 33 40455
E-mail: charlotte.kitchen@dur.ac.uk

Working together to improve forever

Participant ID number:

Information about the study

Who am I?

My name is Charlotte Kitchen, I am a student at Durham University and I also work in Child and Adolescent Mental Health Services.

I would really like to know how you feel about your care.

I want to know which treatments are best for young people who have been feeling low.

This will help us to give young people treatments that they like and find helpful.

What will happen in the study?

We will ask you (and the adult you have brought with you) some questions about yourself.

We can then see if the study is right for you. The study will not be right for everyone.

If we ask you to join the study, you will have either:

1) **Combined Treatment: this could be one or more 'talking' therapies. This is the treatment you would normally have if you were not taking part.**

2) **Behavioural Activation therapy: this will be for eight, one hour sessions. The goal of this therapy is to improve how you feel by changing the way you spend your time. This treatment is not normally offered.**

We are asking you if it is ok for us to give you one of the two options above.

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Participant ID number:

What are the benefits to taking part?

You might get a treatment that you wouldn't normally get.

You will get more time to talk about how you have been feeling.

You can tell us what you like and don't like so we can improve in the future.

You will get £10 in vouchers every time you meet with a researcher as a thank you. You could get up to £30.

Are there any negatives to taking part?

You will not choose which treatment you get, it will be decided by chance (like the toss of a coin). Half of those who take part will have Combined Treatment and the others will have Behavioural Activation.

What will we do with your information?

We won't ask you for much more information than normal. Anything we do ask for will be stored safely and only the research team and your care team will see it.

At the end of the study we will want to tell other people about it. We will never use your name and no one will be able to tell that it was you.

You can say yes or no. It is up to you whether you take part.

If you have any questions please contact Charlotte Kitchen:

0191 33 40455
charlotte.kitchen@dur.ac.uk

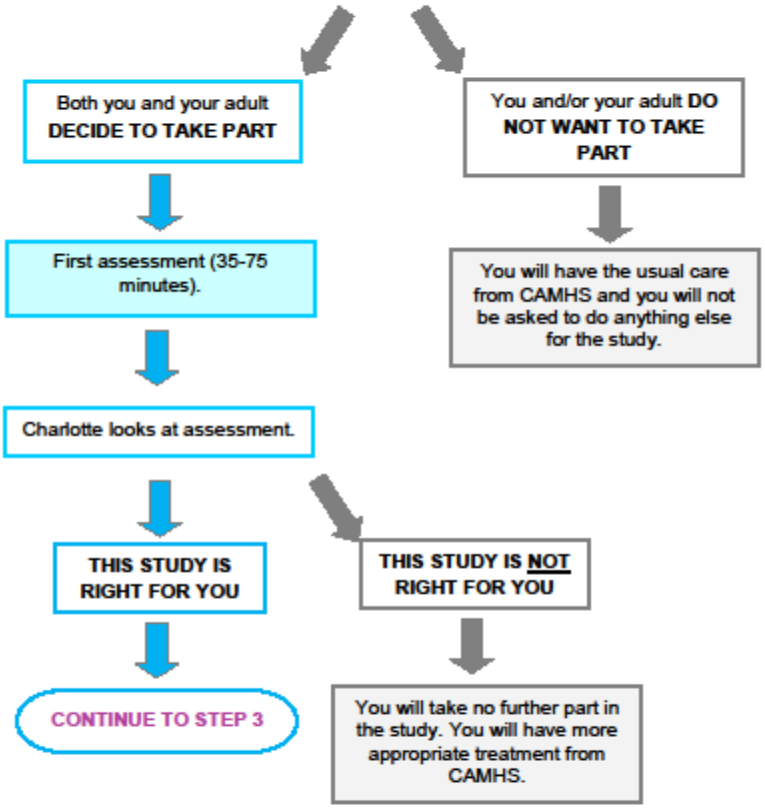
Working together to improve forever

Participant ID number:

What exactly will happen?

STEP 1 **Meet Charlotte today at Child and Adolescent Mental Health Services (CAMHS). Charlotte will explain the study.**

STEP 2 **You and your adult will be asked to take part.**



STEP 3 **Some young people will have the Combined Treatment and others to have Behavioural Activation. A computer will decide who gets which treatment.**

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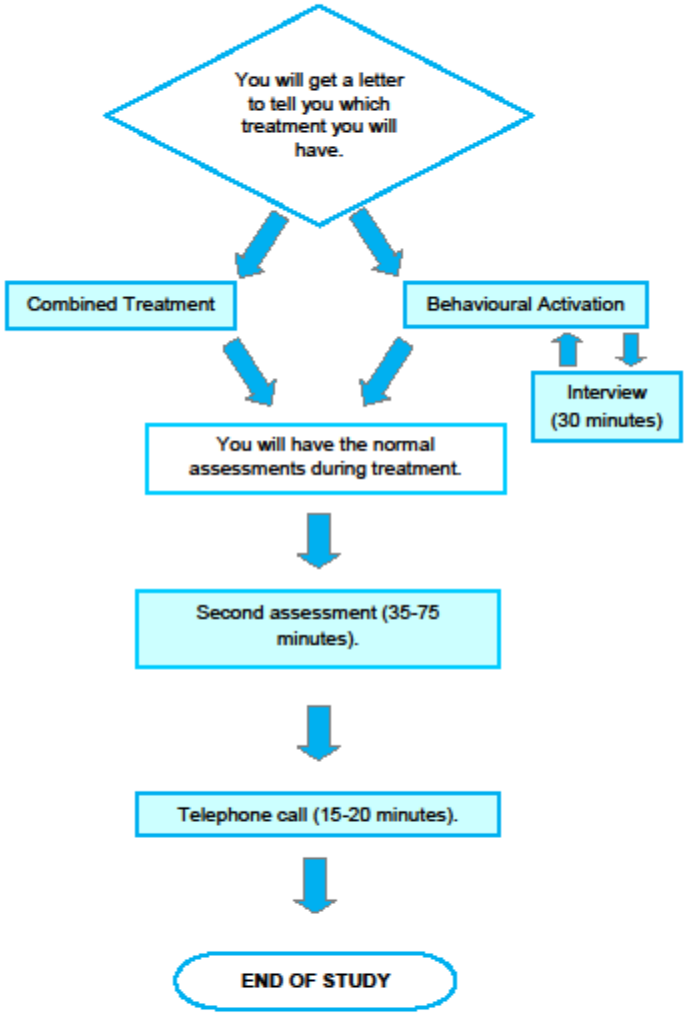
Participant ID number:

STEP 3 Continued



If at **any** time you do <u>not</u> want to take part, you can leave the study and you will not be asked to do anything else (we will only use what you have already given to us).

Working together to improve forever

Participant ID number:

Assent Form

If you would like to take part in 'The BUDDY Study' please read the information below:

1. I have read and understood the information. I have asked any questions I wanted to ask.

2. I know that I can leave the study whenever I want to and I don't need to give a reason. I know that whatever I decide will not affect my care.

3. I understand the researchers will need to see my medical notes.

4. I am happy for the researchers to contact my GP.

5. I know that my treatment sessions will be recorded.

6. The team might use some of the things I have said when they report the study but they will never tell anyone my name.

If you understand the information above, you now need to decide whether you would like to take part in the study.

I want to take part in the study. Tick yes or no.

☐ YES ☐ NO

Your name: ……

Parent/carer name: ……

Date: ……

Signature: ……

Researcher's name: ……

Date: ……

Signature: ……

Working together to improve forever

Participant ID number:

Mood and Feelings Questionnaire– Child Version

This form is about how you have been feeling or acting recently. Please tick the box next to the statement that best describes how you have been feeling or acting over the PAST TWO WEEKS

	Not true	Sometimes	True
1. I felt miserable or unhappy			
2. I didn't enjoy anything at all			
3. I was less hungry than usual			
4. I ate more than usual			
5. I felt so tired I just sat around and did nothing			
6. I was moving and walking more slowly than usual			
7. I was very restless			
8. I felt I was no good anymore			
9. I blamed myself for things that weren't my fault			
10. It was hard for me to make up my mind			
11. I felt grumpy and cross with my parents			
12. I felt like talking less than usual			
13. I was talking more slowly than usual			
14. I cried a lot			
15. I thought there was nothing good for me in the future			
16. I thought that life wasn't worth living			
17. I thought about death or dying			
18. I thought my family would be better off without me			
19. I thought about killing myself			
20. I didn't want to see my friends			
21. I found it hard to think properly or concentrate			
22. I thought bad things would happen to me			

Working together to improve forever

Participant ID number:

Mood and Feelings Questionnaire– Child Version Continued

Please tick the box next to the statement that best describes how you have been feeling or acting over the PAST TWO WEEKS

	Not true	Sometimes	True
23. I hated myself			
24. I felt I was a bad person			
25. I thought I looked ugly			
26. I worried about aches and pains			
27. I felt lonely			
28. I thought nobody really loved me			
29. I didn't have any fun in school			
30. I thought I could never be as good as other kids			
31. I did everything wrong			
32. I didn't sleep as well as I usually sleep			
33. I slept a lot more than usual			

Assessment Date	

MFQ Child Self Report
(http://devepi.duhs.duke.edu/instruments/MFQ%20%20Parent%20Report%20on%20Child%20-

Working together to improve forever

Participant ID number:

Rosenberg's Self-Esteem Scale

Below is a list of statements dealing with your general feelings about yourself. Please tick the box that best describes how you feel about the statement.

	Strongly	Agree	Disagree	Strongly
1. I feel that I am a person of worth, at least on an equal plane with others				
2. I feel that I have a number of good qualities				
3. All in all, I am inclined to feel that I am a failure				
4. I am able to do things as well as most other people				
5. I feel I do not have much to be proud of				
6. I take a positive attitude toward myself				
7. On the whole, I am satisfied with myself				
8. I wish I could have more respect for myself				
9. I certainly feel useless at times				
10. At times I think I am no good at all				

Assessment Date	

Rosenberg's Self-Esteem Scale (http://www.wwnorton.com/college/psych/psychsci/media/rosenberg.htm)

Working together to improve forever

Participant ID number:

Behavioral Activation for Depression Scale

Please read each statement carefully and then tick the box which best describes how much the statement was true for you DURING THE PAST WEEK, INCLUDING TODAY.

0= Not at all 1 2= A little 3 4= A lot 5 6= Completely	1	2	3	4	5	6
1. There were certain things that I needed to do that I didn't do.						
2. I am content with the amount and types of things that I did.						
3. I engaged in many different activities.						
4. I made good decisions about what type of activities and/or situations I put myself in.						
5. I was an active person and accomplished the goals I set out to do.						
6. Most of what I did was to escape from or avoid something unpleasant.						
7. I spent a long time thinking over and over about my problems.						
8. I engaged in activities that would distract me from feeling bad.						
9. I did things that were enjoyable.						
10. At times I think I am no good at all						

Assessment Date	

Kanter, J. W., Mulick, P. S., Busch, A. M., Berlin, K. S., & Martell, C. R. . (2012) . Behavioral Activation for Depression Scale (BADS) (Short Form). Measurement Instrument Database for the Social Science.

Working together to improve forever

Participant ID number:

Thank you for taking the time to complete this workbook.

Working together to improve forever

Participant ID number:

Appendix 8

Stage II: Patient Study Poster

Durham University

Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

The BUDDY Study

We want to know which treatments young people find most helpful for their low mood.

You may be asked to be involved.

Why take part?

- You will have more detailed assessments than normal.
- You will be given one of two treatment options.
- Your feedback will be used to improve care.
- You will be given £10 in vouchers each time you meet with the research team.

We are we looking for?

Young people aged 12 to 17 who have been experiencing low mood or depression.

What will we ask you to do?

- First, we will check you are suitable to take part. To do this, you will need to meet with a researcher for about an hour.
- If you are suitable, you will be treated by your normal professional.
- You will meet with a researcher 3-months later so we can see how you are doing.
- Finally, we will telephone you briefly to see how you are in 6-months time.

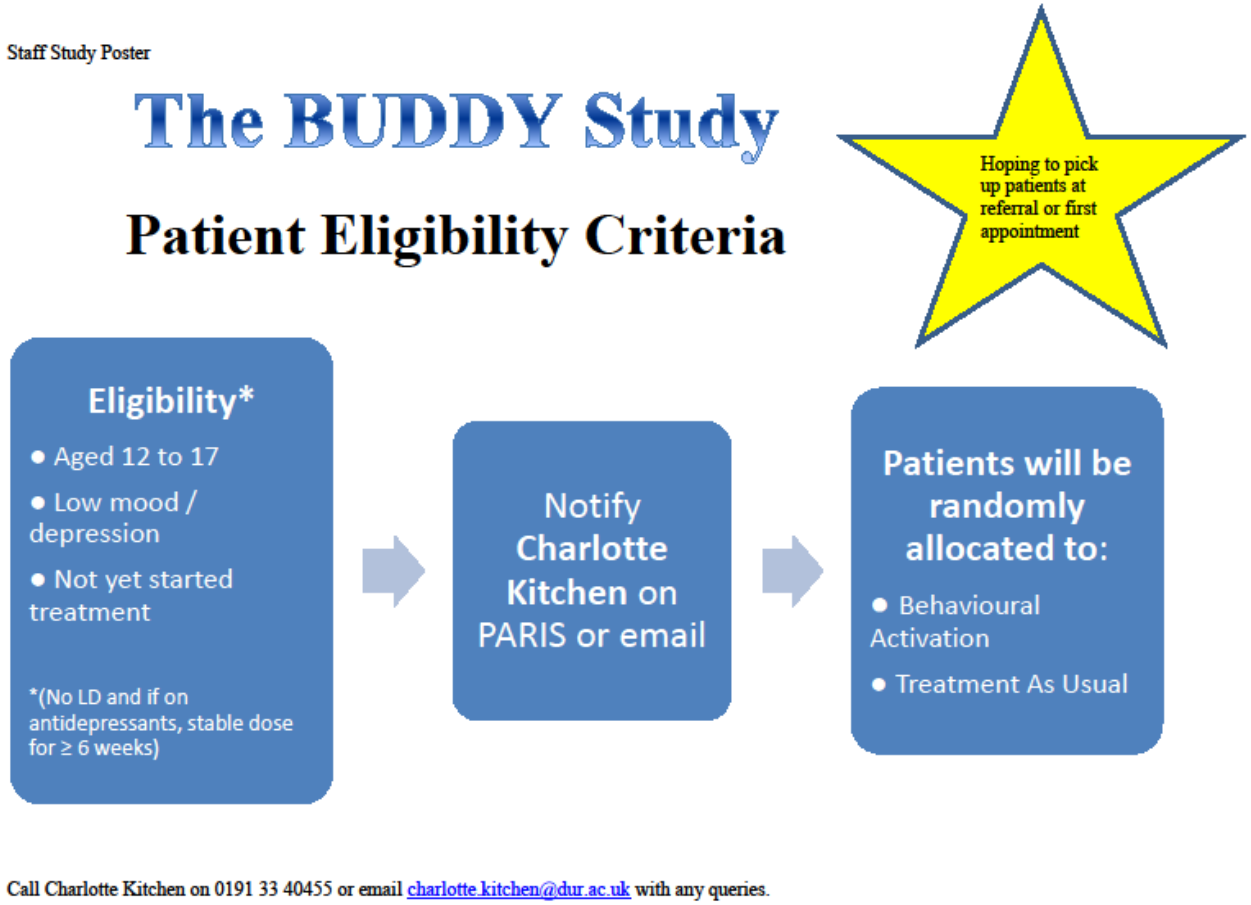
If you are interested in taking part or would like further information about the study please contact Charlotte Kitchen:

Mental Health Research Centre
Durham University Queens Campus
Wolfson Building, University Boulevard, Stockton-On-Tees, TS17 6BH

Tel: 0191 33 40455
Email: charlotte.kitchen@dur.ac.uk

Study Poster Version 3 (26/01/2015)

Stage II: Staff Study Poster



Appendix 9

Stage II: Severity Criteria

(available at http://www.psnpaloalto.com/wp/wp-content/uploads/2010/12/Depression-Diagnostic-Criteria-and-Severity-Rating.pdf)

Diagnostic Criteria for Major Depressive Disorder and Depressive Episodes

DSM-IV Criteria for Major Depressive Disorder (MDD)

- Depressed mood or a loss of interest or pleasure in daily activities for more than two weeks.
- Mood represents a change from the person's baseline.
- Impaired function: social, occupational, educational.
- Specific symptoms, at least 5 of these 9, present nearly every day:
  1. **Depressed mood or irritable** most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful).
  2. **Decreased interest or pleasure** in most activities, most of each day
  3. **Significant weight change (5%) or change in appetite**
  4. **Change in sleep:** Insomnia or hypersomnia
  5. **Change in activity:** Psychomotor agitation or retardation
  6. **Fatigue or loss of energy**
  7. **Guilt/worthlessness:** Feelings of worthlessness or excessive or inappropriate guilt
  8. **Concentration:** diminished ability to think or concentrate, or more indecisiveness
  9. **Suicidality:** Thoughts of death or suicide, or has suicide plan

DSM – V proposed (not yet adopted) anxiety symptoms that may indicate depression: irrational worry, preoccupation with unpleasant worries, trouble relaxing, feeling tense, fear that something awful might happen.

Screen for conditions that may mimic or co exist with Major Depressive Disorder:

- **Substance abuse** causing depressed mood (eg. drugs, alcohol, medications)
- **Medical illness causing depressed mood**
- **Other psychiatric disorders:** mania, hypomania, bipolar, schizoaffective, schizophrenia, etc.
- **Bereavement unless sx persist for > two months or show marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation.**

Depressive Episode Criteria (may be part of Major Depressive Disorder OR an isolated episode)

A	B
Depressed Mood Loss of interest and enjoyment in usual activities Reduced energy and decreased activity	Reduced self esteem and confidence Ideas of guilt and unworthiness Pessimistic thoughts Disturbed sleep Diminished appetite Ideas of self harm

Severity of Depressive Episode:

Mild: > 1 from column A plus 1-2 from column B. Or 5-6 sx but mild in severity and functional impairment.
Moderate: > 1 from column A plus 2-3 from column B. Or 7 – 8 sx but moderate functional impairment.
Severe: All 3 from column A plus > 3 from column B. Or fewer sx but any of these: severe functional impairment, psychotic sx, recent suicide attempt, or has specific suicide plan or clear intent.

Functional Domain	Moderately Impaired	Severely Impaired
Family Relationships	Quiet, negative and oppositional	Withdrawn, won't talk, brusque, angry, aggressive
School & Academics / Work	Grades/work performance deteriorating, missing/cutting class or work, decreased effort, moderate academic or work stress	Failing performance, missing school or work, doesn't care about work, oppositional, argumentative, high academic or work stress
Peer Relationships	Decreased socializing or extracurricular activities , more time on computer	Isolated, discontinued extracurricular activities, excessive computer time
Stress Level, Anxiety	Minimizes or denies issues, projects onto others or blames others	Withholds feelings, won't talk
Suicidal Ideation	Vague/occasional	Frequently considered, has a plan, or prior attempt
Other Self Harm	Occasional thoughts but no attempts	Cutting, other self injury

Appendix 10

Stage II: Parent/Carer Follow-Up Workbook (including Self-Report Follow-Up Outcome Measures)

Durham University

Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

The BUDDY Study

A guide for Parents and Carers of young people under 16

DURHAM UNIVERSITY IN PARTNERSHIP WITH TEES, ESK & WEAR VALLEYS NHS FOUNDATION TRUST

Charlotte Kitchen
Wolfson Building
Durham University Queens Campus
University Boulevard
Stockton-on-Tees, TS17 6BH

Phone: 0191 33 40455
E-mail: charlotte.kitchen@dur.ac.uk

Working together to improve forever

Participant ID number:

Mood and Feelings Questionnaire– Parent Version

This form is about how your child might have been feeling or acting recently. Please tick the box next to the statement that best describes your child over the PAST TWO WEEKS

	Not true	Sometimes	True
1. S/he felt miserable or unhappy			
2. S/he didn't enjoy anything at all			
3. S/he was less hungry than usual			
4. S/he ate more than usual			
5. S/he felt so tired s/he just sat around and did			
6. S/he was moving and walking more slowly than			
7. S/he was very restless			
8. S/he felt s/he was no good anymore			
9. S/he blamed her/himself for things that weren't			
10. It was hard for her/him to make up her/his mind			
11. S/he felt grumpy and cross with you			
12. S/he felt like talking less than usual			
13. S/he was talking more slowly than usual			
14. S/he cried a lot			
15. S/he thought there was nothing good for her/him			
16. S/he thought that life wasn't worth living			
17. S/he thought about death or dying			
18. S/he thought her/his family would be better off			
19. S/he thought about killing her/himself			
20. S/he didn't want to see her/his friends			
21. S/he found it hard to think properly or concen-			
22. S/he thought bad things would happen to her/			

Working together to improve forever

Participant ID number:

Mood and Feelings Questionnaire– Parent Version Continued

Please tick the box next to the statement that best describes your child in the PAST TWO WEEKS

	Not true	Sometimes	True
23. S/he hated him/herself			
24. S/he felt s/he was a bad person			
25. S/he thought s/he looked ugly			
26. S/he worried about aches and pains			
27. S/he felt lonely			
28. S/he thought nobody really loved her/him			
29. S/he didn't have any fun at school			
30. S/he thought s/he could never be as good as other kids			
31. S/he felt s/he did everything wrong			
32. S/he didn't sleep as well as s/he usually sleeps			
33. S/he slept a lot more than usual			
34. S/he wasn't as happy as usual, even when you praised or rewarded her/him			

Assessment Date	

MFQ Parent Report on Child
(http://devepi.duhs.duke.edu/instruments/MFQ%20%20Parent%20Report%20on%20Child%20-

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Participant ID number:

Your Feedback

It is important to us that we hear your views about what worked well for your family and what could be improved about the study and the treatment your young person received.

Please select the option that best reflects what you agree with the most.

1. Did the treatment offered to your young person help them?

☐ Very helpful ☐ Somewhat helpful ☐ Somewhat unhelpful ☐ Very unhelpful

2. How did you feel about the treatment offered to your young person?

☐ Very happy ☐ Somewhat happy ☐ Somewhat unhappy ☐ Very unhappy

3. In the future do you think your young person will use the skills they have learnt during their treatment?

☐ Yes ☐ No

4. Was there anything that you liked or found helpful about the treatment offered to your young person? .....

.....

.....

.....

5. Was there anything you didn't like or anything that was unhelpful about the treatment? .....

.....

.....

.....

6. Is there anything else you would like to tell us about the treatment or involvement in the study?.....

.....

.....

Working together to improve forever

Participant ID number:

Thank you for taking the time to complete this workbook.

Please tick if you would like to receive a copy of the study results

I wish to receive a summary of the results by post or email at the end of the study. *If so please provide your contact details below.*

☐

Address: ……

……

……

Email: ……

Working together to improve forever

Participant ID number:

Stage II: Young Person (aged 16-17) Follow-Up Workbook (including Self-Report Follow-Up Outcome Measures)

Durham University

Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

The BUDDY Study

A Guide for Young People aged 16 and over

DURHAM UNIVERSITY IN PARTNERSHIP WITH TEES, ESK & WEAR VALLEYS NHS FOUNDATION TRUST

Charlotte Kitchen
Wolfson Research Institute
Durham University Queens Campus
University Boulevard
Stockton-on-Tees, TS17 6BH

Phone: 0191 33 40455
E-mail: charlotte.kitchen@dur.ac.uk

Working together to improve forever

Participant ID number:

Mood and Feelings Questionnaire– Child Version

This form is about how you have been feeling or acting recently. Please tick the box next to the statement that best describes how you have been feeling or acting over the PAST TWO WEEKS

	Not true	Sometimes	True
1. I felt miserable or unhappy			
2. I didn't enjoy anything at all			
3. I was less hungry than usual			
4. I ate more than usual			
5. I felt so tired I just sat around and did nothing			
6. I was moving and walking more slowly than usu-			
7. I was very restless			
8. I felt I was no good anymore			
9. I blamed myself for things that weren't my fault			
10. It was hard for me to make up my mind			
11. I felt grumpy and cross with my parents			
12. I felt like talking less than usual			
13. I was talking more slowly than usual			
14. I cried a lot			
15. I thought there was nothing good for me in the			
16. I thought that life wasn't worth living			
17. I thought about death or dying			
18. I thought my family would be better off without			
19. I thought about killing myself			
20. I didn't want to see my friends			
21. I found it hard to think properly or concentrate			
22. I thought bad things would happen to me			

Working together to improve forever

Participant ID number:

Mood and Feelings Questionnaire– Child Version Continued

Please tick the box next to the statement that best describes how you have been feeling or acting over the PAST TWO WEEKS

	Not true	Sometimes	True
23. I hated myself			
24. I felt I was a bad person			
25. I thought I looked ugly			
26. I worried about aches and pains			
27. I felt lonely			
28. I thought nobody really loved me			
29. I didn't have any fun in school			
30. I thought I could never be as good as other kids			
31. I did everything wrong			
32. I didn't sleep as well as I usually sleep			
33. I slept a lot more than usual			

Assessment Date	

MFQ Child Self Report
(http://devepi.duhs.duke.edu/instruments/MFQ%20%20Parent%20Report%20on%20Child%20-

Working together to improve forever

Participant ID number:

Rosenberg's Self-Esteem Scale

Below is a list of statements dealing with your general feelings about yourself. Please tick the box that best describes how you feel about the statement.

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. I feel that I am a person of worth, at				
2. I feel that I have a number of good quali-				
3. All in all, I am inclined to feel that I am a				
4. I am able to do things as well as most				
5. I feel I do not have much to be proud of				
6. I take a positive attitude toward myself				
7. On the whole, I am satisfied with myself				
8. I wish I could have more respect for my-self				
9. I certainly feel useless at times				
10. At times I think I am no good at all				

Assessment Date	

Rosenberg's Self-Esteem Scale (http://www.wwnorton.com/college/psych/psychsci/media/rosenberg.htm)

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Participant ID number:

Behavioral Activation for Depression Scale

Please read each statement carefully and then tick the box which best describes how much the statement was true for you DURING THE PAST WEEK, INCLUDING TODAY.

0= Not at all 1 2= A little 3 4= A lot 5 6= Completely	1	2	3	4	5	6
1. There were certain things that I needed to do that I didn't do.						
2. I am content with the amount and types of things that I did.						
3. I engaged in many different activities.						
4. I made good decisions about what type of activities and/or						
5. I was an active person and accomplished the goals I set out						
6. Most of what I did was to escape from or avoid something						
7. I spent a long time thinking						
8. I engaged in activities that would distract me from feeling						
9. I did things that were						
10. At times I think I am no good						

Assessment Date	

Kanter, J. W., Mulick, P. S., Busch, A. M., Berlin, K. S., & Martell, C. R. . (2012) . Behavioral Activation for Depression Scale (BADS) (Short Form). Measurement Instrument Database for the Social Science.

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Participant ID number:

Your Feedback

It is important to us that we hear your views about what worked well for you and what could be improved about the study and the treatment you received.

Please select the option that best reflects what you agree with the most.

1. Did you find the treatment you were offered helpful?

☐ **Very helpful** ☐ **Somewhat helpful** ☐ **Somewhat unhelpful** ☐ **Very unhelpful**

2. Were you happy with the treatment you were given?

☐ **Very happy** ☐ **Somewhat happy** ☐ **Somewhat unhappy** ☐ **Very unhappy**

3. Would you have preferred the other option of treatment (i.e. the one you did not receive)?

☐ **Yes** ☐ **No** ☐ **Didn't mind**

4. Do you think you will continue to use the skills you have learnt now that your treatment has finished?

☐ **Yes** ☐ **No**

4. Was there anything that you liked or found helpful about your treatment?.....

.....

.....

.....

5. Was there anything you didn't like or anything that was unhelpful about your treatment? .....

.....

.....

.....

6. Is there anything else you would like to tell us about your treatment or involvement in the study?.....

.....

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.....

Working together to improve forever

Participant ID number:

Thank you for taking the time to complete this workbook.

Please tick if you would like to receive a copy of the study results

I wish to receive a summary of the results of the study by post or email. ☐

If so please provide your contact details below.

Address: .....

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Email: .....

Working together to improve forever

Participant ID number:

Stage II: Young Person (aged 12-15) Follow-Up Workbook (including Self-Report Follow-Up Outcome Measures)

Durham University

Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

The BUDDY Study

An Interview Guide for Young People under 16

DURHAM UNIVERSITY IN PARTNERSHIP WITH
TEES, ESK & WEAR VALLEYS NHS FOUNDATION TRUST

Charlotte Kitchen
Wolfson Building
Durham University Queens Campus
University Boulevard
Stockton-on-Tees, TS17 6BH

Phone: 0191 33 40455
E-mail: charlotte.kitchen@dur.ac.uk

Working together to improve forever

Participant ID number:

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	Not true	Sometimes	True
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2. I didn't enjoy anything at all			
3. I was less hungry than usual			
4. I ate more than usual			
5. I felt so tired I just sat around and did nothing			
6. I was moving and walking more slowly than usu-			
7. I was very restless			
8. I felt I was no good anymore			
9. I blamed myself for things that weren't my fault			
10. It was hard for me to make up my mind			
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13. I was talking more slowly than usual			
14. I cried a lot			
15. I thought there was nothing good for me in the			
16. I thought that life wasn't worth living			
17. I thought about death or dying			
18. I thought my family would be better off without			
19. I thought about killing myself			
20. I didn't want to see my friends			
21. I found it hard to think properly or concentrate			
22. I thought bad things would happen to me			

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Participant ID number:

Mood and Feelings Questionnaire– Child Version Continued

Please tick the box next to the statement that best describes how you have been feeling or acting over the PAST TWO WEEKS

	Not true	Sometimes	True
23. I hated myself			
24. I felt I was a bad person			
25. I thought I looked ugly			
26. I worried about aches and pains			
27. I felt lonely			
28. I thought nobody really loved me			
29. I didn't have any fun in school			
30. I thought I could never be as good as other kids			
31. I did everything wrong			
32. I didn't sleep as well as I usually sleep			
33. I slept a lot more than usual			

Assessment Date	

MFQ Child Self Report
(http://devepi.duhs.duke.edu/instruments/MFQ%20%20Parent%20Report%20on%20Child%20-

Working together to improve forever

Participant ID number:

Rosenberg's Self-Esteem Scale

Below is a list of statements dealing with your general feelings about yourself. Please tick the box that best describes how you feel about the statement.

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2. I feel that I have a number of good quali-				
3. All in all, I am inclined to feel that I am a				
4. I am able to do things as well as most				
5. I feel I do not have much to be proud of				
6. I take a positive attitude toward myself				
7. On the whole, I am satisfied with myself				
8. I wish I could have more respect for my-self				
9. I certainly feel useless at times				
10. At times I think I am no good at all				

Assessment Date	

Rosenberg's Self-Esteem Scale (http://www.wwnorton.com/college/psych/psychsci/media/rosenberg.htm)

Working together to improve forever

Participant ID number:

Behavioral Activation for Depression Scale

Please read each statement carefully and then tick the box which best describes how much the statement was true for you DURING THE PAST WEEK, INCLUDING TODAY.

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2. I am content with the amount and types of things that I did.						
3. I engaged in many different activities.						
4. I made good decisions about what type of activities and/or						
5. I was an active person and accomplished the goals I set out						
6. Most of what I did was to escape from or avoid something						
7. I spent a long time thinking						
8. I engaged in activities that would distract me from feeling						
9. I did things that were						
10. At times I think I am no good						

Assessment Date	

Kanter, J. W., Mulick, P. S., Busch, A. M., Berlin, K. S., & Martell, C. R. . (2012) . Behavioral Activation for Depression Scale (BADS) (Short Form). Measurement Instrument Database for the Social Science.

Working together to improve forever

Participant ID number:

Your Feedback

It is important to us that we hear your views about what worked well for you and what could be improved about the study and the treatment you received.

Please select the option that best reflects what you agree with the most.

1. Did you find the treatment you were offered helpful?

☐ **Very helpful** ☐ **Somewhat helpful** ☐ **Somewhat unhelpful** ☐ **Very unhelpful**

2. Were you happy with the treatment you were given?

☐ **Very happy** ☐ **Somewhat happy** ☐ **Somewhat unhappy** ☐ **Very unhappy**

3. Would you have preferred the other option of treatment (i.e. the one you did not receive)?

☐ **Yes** ☐ **No** ☐ **Didn't mind**

4. Do you think you will continue to use the skills you have learnt now that your treatment has finished?

☐ **Yes** ☐ **No**

5. Was there anything that you liked or found helpful about your treatment?.....

.....

.....

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6. Was there anything you didn't like or anything that was unhelpful about your treatment? .....

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7. Is there anything else you would like to tell us about your treatment or involvement in the study?.....

.....

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.....

Working together to improve forever

Participant ID number:

Thank you for taking the time to complete this workbook.

Please tick if you would like to receive a copy of the study results

I wish to receive a summary of the results of the study by post or email. ☐

If so please provide your contact details below.

Address: .....

.....

.....

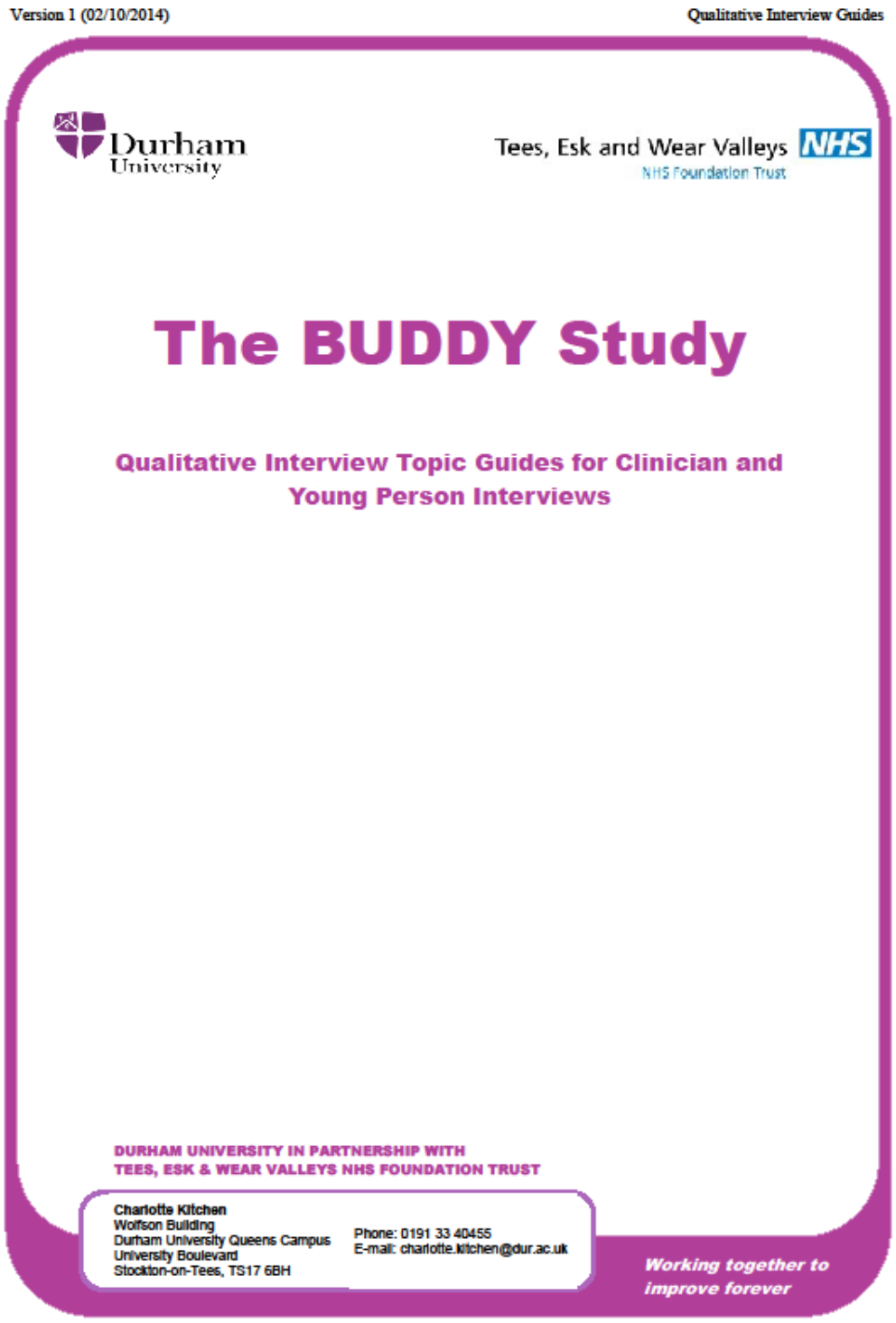
Email: .....

Working together to improve forever

Participant ID number:

Appendix 11

Stage II: Interview Topic Guides



Topic Guide for Young Person (and Parent/Carer[s])

The format of the qualitative interview will follow the topic guide below starting off with general open-ended questions followed by a series of areas to probe or more specific questions.

1. Recruitment

Could you tell us how you became involved in '*The BUDDY Study*' ?

Probes:
How did you feel about the way you were first contacted (i.e. letter)?
Would there have been a better way to ask you to take part?

2. Treatment allocation

At the start of '*The BUDDY Study*' you were allocated to the Behavioural Activation (BA) treatment option. How did you feel about the two options for treatment that you were offered?

Probes:
Were you happy with the treatment you were allocated?
Did you have a preference for one treatment over another?
Were there any other treatment options that you would have liked to have been offered?

3. General experiences of treatment

You recently received BA; please tell me about your experiences of receiving this treatment.

Probes:
What did it feel like receiving treatment?
Was there anything in particular that you liked or found helpful?
Was there anything that you didn't like or found less helpful?

4. Format of treatment

We would like to hear your thoughts on the delivery of therapy; please tell me about your experiences of the number and length of the therapy sessions.

Probes:
Did the number of sessions feel enough, just right or too many?
Were the individual sessions too long, too short or just right?
Was a week in between sessions about right, too short or too long?

5. Parental involvement in therapy

We are interested to find out whether young people wanted their parent/carer(s) to be involved in their therapy or not. Please tell me about your parents or carers role in your treatment.

Probes:
How did you feel about your parent/carer(s) involvement?
Would you have preferred they were involved more or less or was it about right?

6. Barriers to treatment

We are interested in the reasons why people might miss therapy sessions and why others might attend them all. Please tell me about your attendance at sessions.

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Topic Guide Continued

Probes:
What were your reasons for continuing or stopping therapy?
What factors affected whether or not you completed the tasks you were set by your therapist?
Were there any particular stages of treatment or tasks that you found difficult?
Was there anything (else) that could have been done to overcome these difficulties?
Personal contextual factors
Specific therapy factors
Therapeutic relationship factors

7. Cognitive change strategies

We are interested to see if therapy may have changed the way you think, in any way. Did the therapy have any effect on your beliefs or the way you think? We also would like to know, if it did, did this have any impact on your mood?

Probes:
Underlying beliefs
Style of thinking
Influence of the changes in the way they think about mood/depression

8. Behavioural change strategies

We are interested to know whether you think therapy changed your behaviour in any way. Did you notice any effect on your behaviour and if so, did these behaviour changes have any impact on your mood?

Probes:
Changes in specific behaviours (e.g. avoidance, rumination)
Recognising triggers and changing behaviour in response to them
Influence of behavioural changes on mood/depression

9. Most important part of therapy

Please tell us about the most important parts of therapy for you.

Probes:
Therapeutic relationship
Exercises/homework tasks

10. Broader impact of treatment

Please tell us about the impact the treatment had on you generally or in other aspects of your life.

Probes:
Thoughts and opinions on depression
The way they feel about themselves
The role of psychological therapies in the treatment of depression
Impact of treatment on any other areas of life
If you have made changes, do you think you can keep them up?

11. Any other thoughts

Please tell us about any other thoughts you had on the treatment that you received.

Working together to improve forever

Topic Guide for Clinician Interviews

1. Recruitment

How successful do you think the recruitment strategy was for '*The BUDDY Study*' ?

Probes:
Would there have been a better way to ask families to take part?

2. General experiences of treatment

You recently administered Behavioural Activation (BA) to young people. Please tell me about your experiences of providing this treatment.

Probes:
What did it feel like providing this treatment?
Was there anything in particular that you liked or found helpful?
Was there anything that you didn't like or found less helpful?

3. Format of treatment and manual

We would like to hear your thoughts on the layout of the therapy and manual. Please tell me your experiences of the number and length of the therapy sessions and using the treatment manual.

Probes:
Did the number of sessions feel enough, just right or too many?
Was a week in between sessions about right?
Did you identify any problems with the format of the therapy?
Did you identify any problems with the format or content of the manual?

4. Parental involvement in therapy

We are interested to find out whether parent/carer(s) involvement in therapy was valuable or not. Please tell us about your thoughts on parent/carer involvement in treatment.

Probes:
Was it helpful to have parents/carers involved?
Were there times when it wasn't helpful?
Would you have preferred they were involved more or less?

5. Barriers to treatment

We are interested in the reasons why some young people might decide not to attend some of their therapy sessions. Similarly, why young people often complete some exercises or tasks and maybe not others. Please tell us about your thoughts on this.

Probes:
Personal contextual factors
Specific therapy factors
Therapeutic relationship factors
Were there any particular stages of treatment or tasks that young people found difficult?
Was there anything (else) that could have been done to overcome these difficulties?

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Topic Guide for Clinicians Continued

6. Cognitive change strategies

We are interested to see if therapy may have changed the way young people think, in any way. Did you find that the therapy affected young people's beliefs or the way they think? If so, did this have any impact on their mood?

Probes:
Underlying beliefs
Style of thinking
Influence of the changes in the way they think about mood/depression

7. Behavioural change strategies

We are interested to know whether you think therapy changed the young people's behaviour in any way. Did you notice any effects and if so, did these behaviour changes have any impact on their mood?

Probes:
Changes in specific behaviour, e.g. avoidance, rumination
Recognising triggers and changing behaviour in response to them
Influence of behavioural changes on mood/depression

8. Most important part of therapy

Please tell me what you thought was the most important part of therapy.

Probes:
Therapeutic relationship
Exercises/homework tasks

9. Broader impact of treatment

Please tell us about any wider impact you noticed the treatment had on the young people or their families.

Probes:
Thoughts and opinions on depression
The way they felt about themselves
The role of psychological therapies in the treatment of depression
Impact of treatment on any other areas of life
If you noticed changes, do you think they can keep them up?

10. Any other thoughts

Please tell us about any other thoughts you had on the treatment that you provided.

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Appendix 12

Stage II: Clinician Interview Information Sheet and Consent Form

Durham University

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NHS Foundation Trust

The BUDDY Study

Clinician Information sheet and consent form for the Qualitative Interview

DURHAM UNIVERSITY IN PARTNERSHIP WITH TEES, ESK & WEAR VALLEYS NHS FOUNDATIN TRUST

Charlotte Kitchen
Wolfson Building
Durham University Queens Campus
University Boulevard
Stockton-on-Tees, TS17 6BH

Phone: 0191 33 40455
E-mail: charlotte.kitchen@dur.ac.uk

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ID number:

Information Sheet

We are asking you to attend an interview with a researcher to talk about your experience of deploying Behavioural Activation Therapy.

We really want to hear about your personal experience of taking part in the BUDDY study and delivering Behavioural Activation using the manual. This will help us to understand what works well and what we need to improve. The result will be a better package of treatment which will hopefully improve patient experience in the future.

How long will the interview take?

That depends on you; we think it will take around 30 minutes but it may be shorter or longer depending on your feedback. We would like as much detail as you can provide.

What will we do with the information collected?

The interview will be audio recorded using a Trust approved recorder. These recordings will be securely destroyed once we have obtained a written version of the conversation for analysis. The remaining data will be stored confidentially at the university inline with NHS and university policies.

When we have finished the study we will inform others about what we have found; we might use quotes but it will be impossible for others to realise which members of staff have taken part and you will never be named.

You do not have to agree to take part and there will be no penalties for not participating.

Even if you do decide to take part you can change your mind at anytime during the interview.

If you have any questions please contact Charlotte Kitchen:

0191 33 40455
charlotte.kitchen@dur.ac.uk

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ID number:

Consent Form

PROJECT TITLE: The BUDDY Study Interview

Please initial each box to confirm that you agree with each statement

I have read and understood the information sheet. I have had the opportunity to consider the information and ask questions. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time during the interview without giving a reason. I understand that if I do withdraw, any information collected up until that point will be kept and used as part of the research. ☐

I understand that the interview will be audio recorded. ☐

I agree to the use of anonymised quotes when this research is published. ☐

I agree to take part in the above study. ☐

Name: ……

Date: ……

Signature: ……

Name of Person taking Consent: ……

Date: ……

Signature: ……

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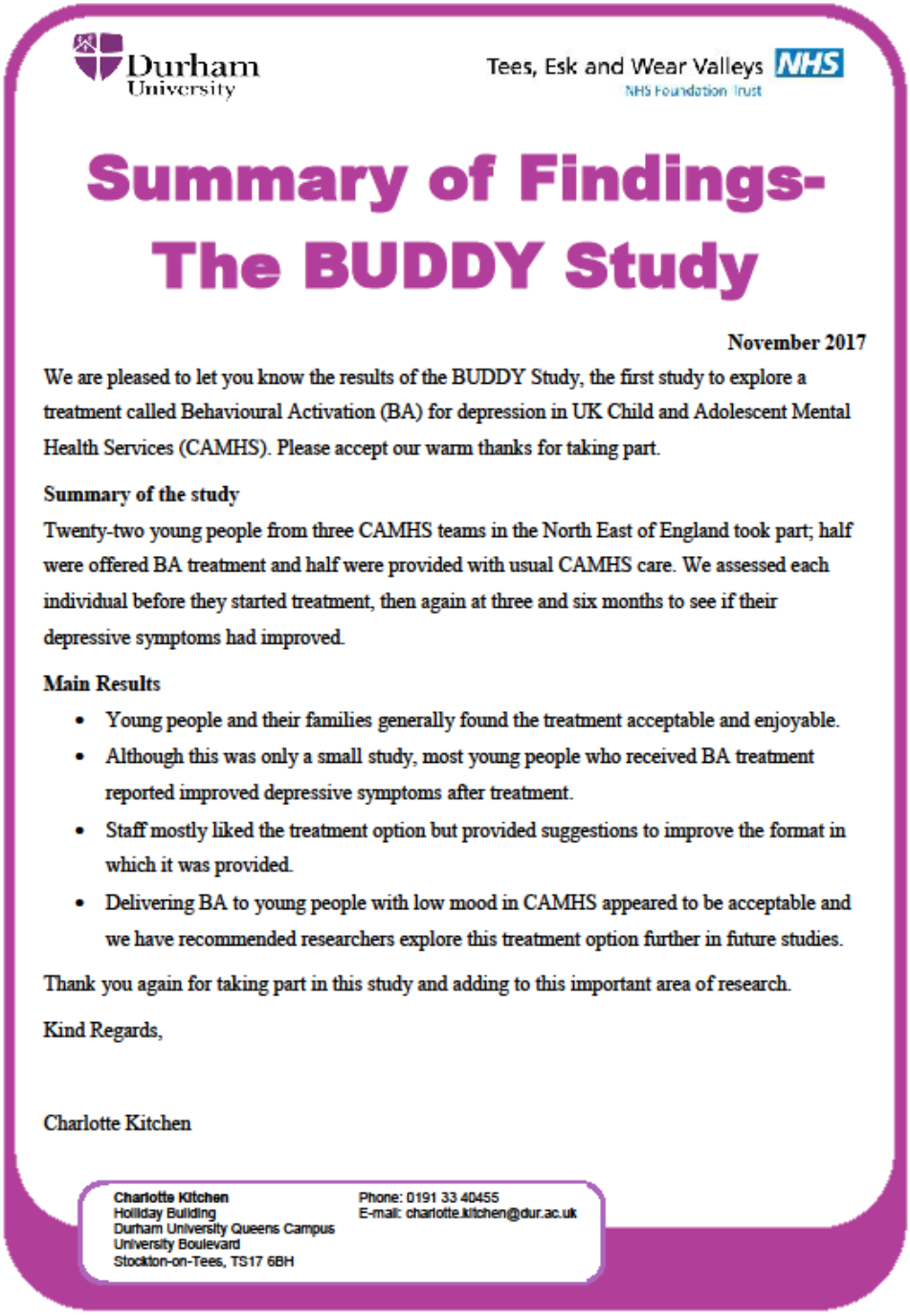
ID number:

Appendix 13

Stage II: Participant Lay Results Summary



Durham University

Tees, Esk and Wear Valleys NHS
NHS Foundation Trust

Summary of Findings- The BUDDY Study

November 2017

We are pleased to let you know the results of the BUDDY Study, the first study to explore a treatment called Behavioural Activation (BA) for depression in UK Child and Adolescent Mental Health Services (CAMHS). Please accept our warm thanks for taking part.

Summary of the study

Twenty-two young people from three CAMHS teams in the North East of England took part; half were offered BA treatment and half were provided with usual CAMHS care. We assessed each individual before they started treatment, then again at three and six months to see if their depressive symptoms had improved.

Main Results

- Young people and their families generally found the treatment acceptable and enjoyable.
- Although this was only a small study, most young people who received BA treatment reported improved depressive symptoms after treatment.
- Staff mostly liked the treatment option but provided suggestions to improve the format in which it was provided.
- Delivering BA to young people with low mood in CAMHS appeared to be acceptable and we have recommended researchers explore this treatment option further in future studies.

Thank you again for taking part in this study and adding to this important area of research.

Kind Regards,

Charlotte Kitchen

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Appendix 14

Stage II: Overview of the care provided to participants assigned to treatment as usual

Pseudonym	Gender	Tier	Service Contact at 3-month follow-up	No. Treatment Sessions: 3-months	Service Contact at 6-month follow-up	No. Treatment Sessions: 6-months
Joseph	m	3	Discharged without further assessment or treatment.	0	One-hour individual assessment session.	0
Rhiannon	f	2	One assessment session.	0	One-hour individual assessment session and one treatment session.	1
Kristen	f	2	None given.	0	None given.	0
Caseigh	f	3	Discharged without further assessment due to no response to a 14-day letter.	0	Discharged.	0
Amber	f	3	One half an hour assessment session, two one-hour CBT sessions, one 50-minute CBT session, one CBT session of an unspecified length, one brief care-coordination review with parent.	4	Discharged due to no response to a 14-day letter.	0
Antonia	f	2	One 'CBT inspired' appointment for an unspecified time, one one-hour 'skills training (psychological wellbeing)'/ 'CBT inspired' session,	9	Four one-hour and one 40-minute 'coping strategies (psychological wellbeing)' sessions, one appointment	6

			six one-hour 'coping strategies (psychological wellbeing)'/CBT sessions, one 50-minute 'coping strategies (psychological wellbeing)' and one 15-minute care-coordination review with parent.		with a medic for an unspecified time and one review meeting with a parent.	
Ben	m	2	One half an hour information giving/assessment session.	0	One-hour information giving/assessment session, one-hour EIP assessment session, one-hour 'First Episode Pathway' treatment session, 10-minute physical health appointment.	1
Alannah	f	2	One-hour group therapy session.	1	None given.	0
Laura	f	2	Four 45-minute and one half an hour CBT appointments.	5	Discharged.	0
Isabel	f	3	One 45-minute discharge meeting.	0	Discharged.	0
Megan	f	2	One 50-minute assessment session.	0	None given.	0

Appendix 15

Stage II: Overview of the care provided to participants assigned to Behavioural Activation treatment

Pseudonym	Gender	Tier	Service Contact at 3-month follow-up	No. Treatment Sessions: 3-months	Service Contact at 6-month follow-up	No. Treatment Sessions: 6-months
Jennifer	f	3	Two BA sessions over four weeks (one 60 and one 55-minutes), one unspecified session.	2	Cognitive Assessment, one 45-minute family therapy (systemic) session, 10-minute care coordination meeting with social worker, one-hour CBT assessment, one-hour care review with family. Discharged due to non-attendance at two anger management sessions.	1
Frankie	f	3	Three BA sessions over six weeks (two 45 and one 50-minutes), one 50-minute assessment and one 45-minute medication monitoring appointment.	4	One unspecified 45-minute treatment session and one 30-minute medication monitoring appointment. Discharged to GP.	1
David	m	3	Two 10-minute medication reviews, one medication review (unspecified time), one 40 and one 35-minute medication monitoring	8	None.	0

			sessions, one one-hour assessment session, eight BA sessions over 13 weeks (seven 30 and one 45 minutes).			
Jessica	f	2	No response to 14 day letter. Discharged.	0	Discharged.	0
Estelle	f	2	One 50-minute assessment, eight BA sessions over 11 weeks (one 30, two 45, one 55 and three 60-minutes).	8	Discharged. Referred back into the service.	0
Lucy	f	2	One-hour initial assessment, eight BA sessions over 8 weeks (one 45, three 60, two 65, one 70 and one 75-minutes). Discharged with no review.	8	Discharged.	0
Sophie	f	2	One 70-minute assessment session, one 45-minute BA session, one unidentified session (appeared to be CBT content) for one-hour. Deemed at this point unsuitable for BA treatment by clinician.	2	Transferred to Tier 3 for treatment.	Excluded from study.
Victoria	f	2	Seven BA sessions over 9 weeks (one 55, two 50, two 45 and two 40-minutes), 80-minute school review, one 35-minute unspecified session, one 45-minute information giving session and a 35 and a 45-minute review. After not	11	Discharged.	0

			attending the final review, she was discharged.			
Connor	m	2	One 50-minute assessment, four BA sessions over 8 weeks (one 30, one 45 and one 60-minutes, one delivered over two sessions of 20 and 60-minutes). Did not attend next appointment. Discharged.	4	Discharged. Referral back into service from the Youth Offending Service.	0
Neive	f	2	One one-hour assessment session, three BA sessions over six weeks (one 45, one 50-minutes and one delivered over a 30 and 15-minute session). Terminated treatment as family wished to focus on exam anxiety.	3	One 30-minute review.	0
Alicia	f	3	Eight one-hour BA sessions over 8-weeks and one BA feedback session to a parent.	8	One 90-minute group therapy assessment, six 90-minute sessions group therapy, one 60 and one 90-minute BA review session.	6